

# Pregnant and Postpartum Care for People with Substance Use Disorder During the COVID-19 Pandemic

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# Brief History of SARS-CoV-2/COVID-19

- Novel corona virus identified December 2019 as cause of pneumonia cluster in Wuhan – led to rapid outbreak in China
- Designated severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) – February 2020 WHO designated the disease COVID-19 (coronavirus disease 2019)
- WHO Pandemic early March
- Route of transmission: respiratory droplets (direct or indirect – from infected surfaces)
- Incubation Period - 14 days from exposure to symptoms
- Symptoms – Cough, Fever, SOB, Chills, Muscle Pain, Sore Throat, New Loss of Taste or Smell
- Illness Spectrum
  - 81% Mild (mild or no pneumonia)
  - 14% Severe (dyspnea, hypoxia, or >50% lung involvement)
  - 5% Critical (respiratory failure, shock)
  - Death Rate – 3.4% globally (range 0.6 South Korea - 12% Wuhan time delay analysis)
- Risk Factors: Age and underlying medical comorbidities (pulmonary)
  - However 20% of hospitalizations are adults 20-44 yo

# What makes this virus so dangerous

- Novel – Information still evolving
- Virus is stable in aerosols for hours
- Highly transmissible – average infection > 2 people
- Resource intensive (for serious illness 2-3 week ICU admission)
- Limited prevention and no treatment (aside from supportive care)
- Therefore: Social Distancing, Face Masks, and Hand washing

### Key Summary Points

The likelihood that approximately 40% to 45% of those infected with SARS-CoV-2 will remain asymptomatic suggests that the virus might have greater potential than previously estimated to spread silently and deeply through human populations.

Asymptomatic persons can transmit SARS-CoV-2 to others for an extended period, perhaps longer than 14 days.

The absence of COVID-19 symptoms in persons infected with SARS-CoV-2 might not necessarily imply an absence of harm. More research is needed to determine the significance of subclinical lung changes visible on computed tomography scans.

The focus of testing programs for SARS-CoV-2 should be substantially broadened to include persons who do not have symptoms of COVID-19.

## Prevalence of Asymptomatic SARS-CoV-2 Infection

### A Narrative Review

Daniel P. Oran, AM, and Eric J. Topol, MD

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has spread rapidly throughout the world since the first cases of coronavirus disease 2019 (COVID-19) were observed in December 2019 in Wuhan, China. It has been suspected that infected persons who remain asymptomatic play a significant role in the ongoing pandemic, but their relative number and effect have been uncertain. The authors sought to review and synthesize the available evidence on asymptomatic SARS-CoV-2 infection. Asymptomatic persons seem to account for approximately 40% to 45% of SARS-CoV-2 infections, and they can transmit the virus to others for an extended period, perhaps longer than 14 days. Asymptomatic infection may be associated with subclinical lung

abnormalities, as detected by computed tomography. Because of the high risk for silent spread by asymptomatic persons, it is imperative that testing programs include those without symptoms. To supplement conventional diagnostic testing, which is constrained by capacity, cost, and its one-off nature, innovative tactics for public health surveillance, such as crowdsourcing digital wearable data and monitoring sewage sludge, might be helpful.

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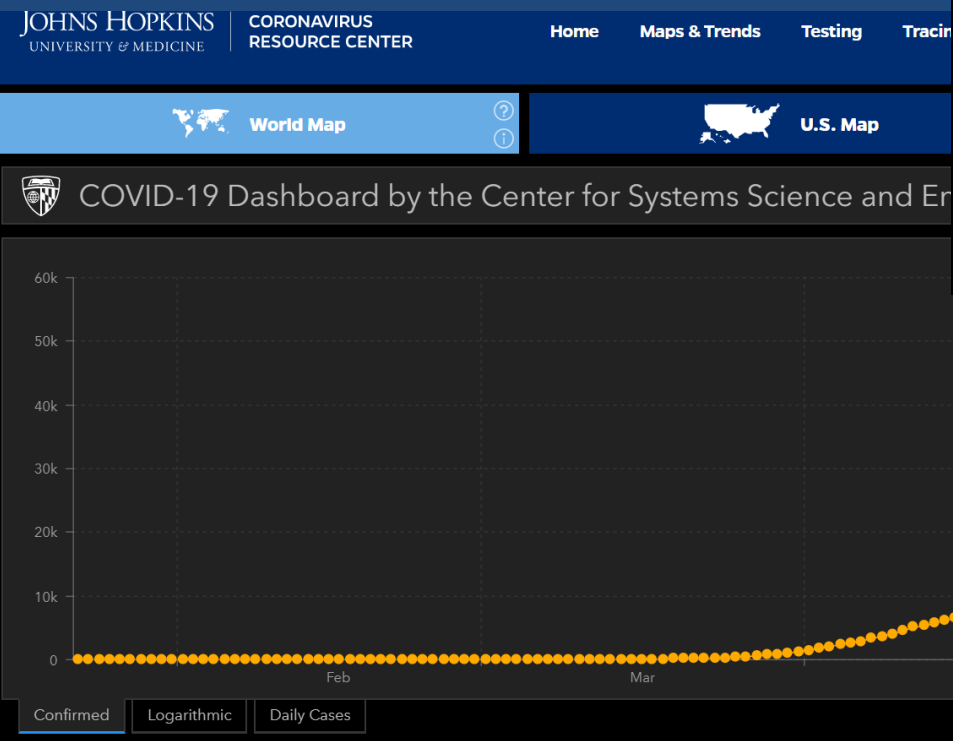
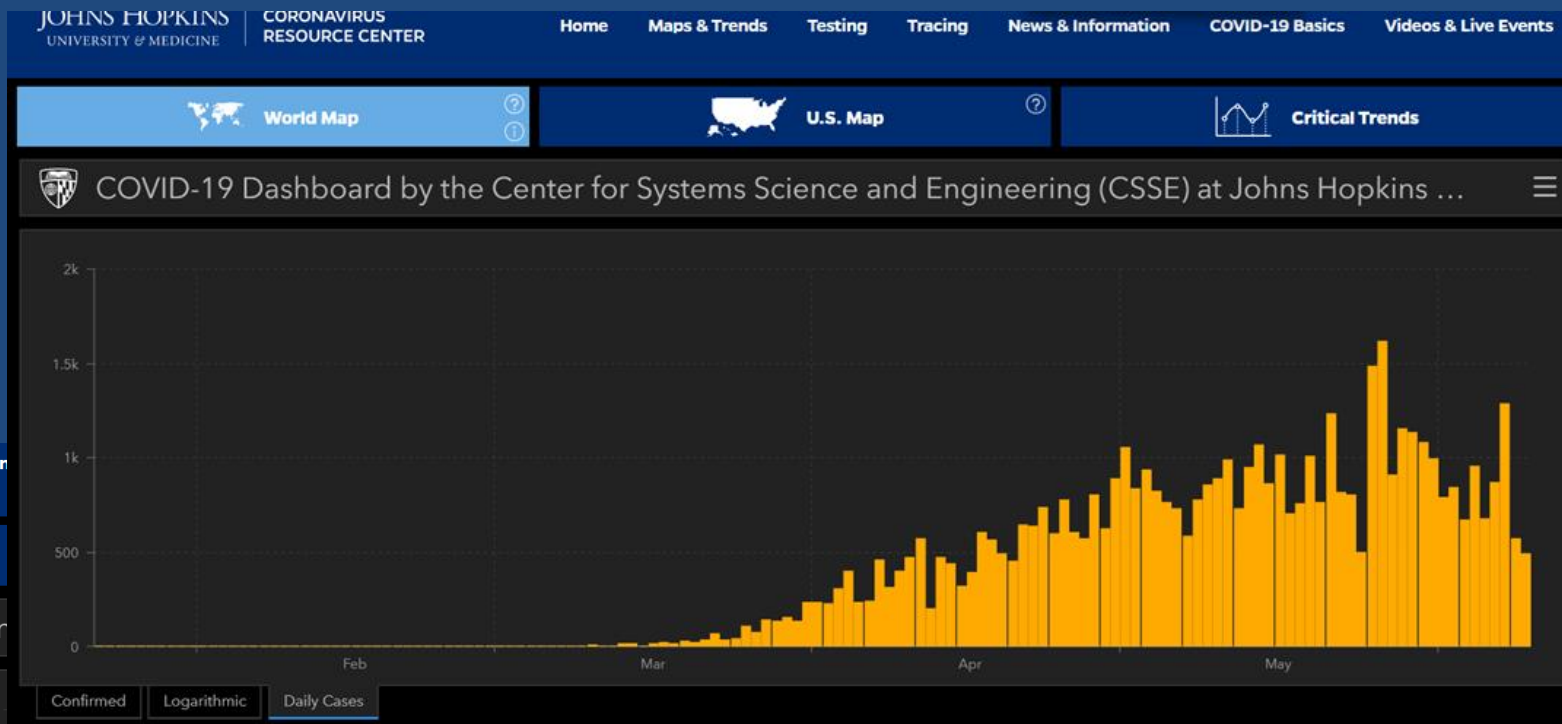
For author, article, and disclosure information, see end of text. This article was published at Annals.org on 3 June 2020.

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Table. Summary of SARS-CoV-2 Testing Studies

Cohort	Tested, n	SARS-CoV-2 Positive, n (%)	Positive but Asymptomatic, n (%)
Iceland residents (6)	13 080	100 (0.8)	43 (43.0)
Vo', Italy, residents (7)	5155	102 (2.0)	43 (42.2)
Diamond Princess cruise ship passengers and crew (8)	3711	712 (19.2)	331 (46.5)
Boston homeless shelter occupants (9)	408	147 (36.0)	129 (87.8)
New York City obstetric patients (11)	214	33 (15.4)	29 (87.9)
U.S.S. Theodore Roosevelt aircraft carrier crew (12)	4954	856 (17.3)	~500 (58.4)
Japanese citizens evacuated from Wuhan, China (2)	565	13 (2.3)	4 (30.8)
Greek citizens evacuated from the United Kingdom, Spain, and Turkey (14)†	783	40 (5.1)	35 (87.5)
Charles de Gaulle aircraft carrier crew (13)	1760	1046 (59.4)	~500 (47.8)
Los Angeles homeless shelter occupants (10)	178	43 (24.2)	27 (62.8)
King County, Washington, nursing facility residents (15)	76	48 (63.2)	3 (6.3)
Arkansas, North Carolina, Ohio, and Virginia inmates (16)	4693	3277 (69.8)	3146 (96.0)
New Jersey university and hospital employees (17)	829	41 (4.9)	27 (65.9)
Indiana residents (18)	4611	78 (1.7)	35 (44.8)
Argentine cruise ship passengers and crew (19)	217	128 (59.0)	104 (81.3)
San Francisco residents (29)	4160	74 (1.8)	39 (52.7)

# COVID-19 Virginia



Retrieved 6/10/20



RESEARCH LETTER

Association of Stay-at-Home Orders With COVID-19 Hospitalizations in 4 States

In analyses of the effectiveness of response measures to the outbreak of coronavirus disease 2019 (COVID-19), most studies have used the number of confirmed cases or deaths. However, case count is a conservative estimate of the actual number of infected individuals in the absence of community-wide serologic testing. Death count is a lagging metric and insufficient for proactive hospital capacity planning. A more valuable metric for assessing the effects of public health interventions on the health care infrastructure is hospitalizations.<sup>1</sup> As of April 18, 2020, governors in 42 states had issued statewide executive “stay-at-home” orders to help mitigate the risk that COVID-19 hospitalizations would overwhelm their state’s health care infrastructure. This study assessed the association between these orders and hospitalization trends.

**Methods** | In March 2020, we began collecting data on cumulative confirmed COVID-19 hospitalizations from each state’s department of health website on a daily basis.<sup>2</sup> Among states issuing a statewide stay-at-home order, we identified states with at least 7 consecutive days of cumulative hospitalization data for COVID-19 (including patients currently hospitalized and those discharged) before the stay-at-home order date and at least 17 days following the order date. Because the median incubation period of COVID-19 was reported to be 4 to 5.1 days<sup>3,4</sup> and the median time from first symptom to hospitalization was found to be 7 days,<sup>5</sup> we hypothesized that any association between stay-at-home orders and hospitalization rates would become evident after 12 days (median effective date). States included in this sample were Colorado, Minnesota, Ohio, and Virginia. Among the 4 states meeting the inclusion criteria, the earliest date with data on hospitalizations was March 10. All states were observed through April 28. We fit the best exponential growth function to cumulative hospitalization data in each state for dates up to and

including the median effective date of that state’s stay-at-home order. We computed 95% prediction bands on the exponential fit line to determine if the observed number of hospitalizations fell within the interval. We then examined whether the observed cumulative hospitalizations for dates after the median effective date deviated from the projected exponential growth in cumulative hospitalizations. In an additional analysis, a linear growth function was fit to cumulative hospitalization data for dates up to and including the median effective date, and goodness of fit was assessed with an  $R^2$  comparison. All analyses were performed using Microsoft Excel version 14.1.

**Results** | In all 4 states, cumulative hospitalizations up to and including the median effective date of a stay-at-home order closely fit and favored an exponential function over a linear fit ( $R^2 = 0.973$  vs 0.695 in Colorado; 0.965 vs 0.865 in Minnesota; 0.98 vs 0.803 in Ohio; 0.994 vs 0.775 in Virginia) (Table). However, after the median effective date, observed hospitalization growth rates deviated from projected exponential growth rates with slower growth in all 4 states. Observed hospitalizations consistently fell outside of the 95% prediction bands of the projected exponential growth curve (Figure).

For example, Minnesota’s residents were mandated to stay at home starting March 28. On April 13, 5 days after the median effective date, the cumulative projected hospitalizations were 988 and the actual hospitalizations were 361. In Virginia, projected hospitalizations 5 days after the median effective date were 2335 and actual hospitalizations were 1048.

**Discussion** | In 4 states with stay-at-home orders, cumulative hospitalizations for COVID-19 deviated from projected best-fit exponential growth rates after these orders became effective. The deviation started 2 to 4 days sooner than the median effective date of each state’s order and may reflect the use of a median incubation period for symptom onset and time to

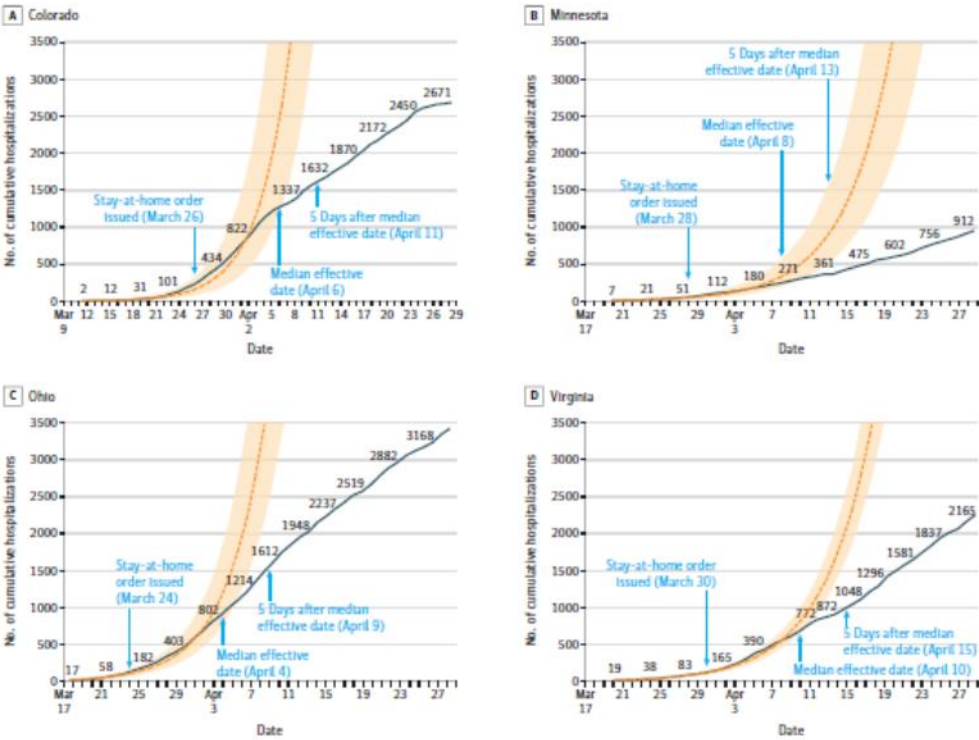
Table. Cumulative Hospitalizations Due to COVID-19 in Colorado, Minnesota, Ohio, and Virginia, March 10 Through April 28, 2020

State	Fitting period*	Stay-at-home issue date	Median effective date	Cumulative hospitalizations		Best exponential fit: $\ln(y) = \ln(a) + bt$			Linear fit: $y = ct$	
				On first day of reporting	On April 28	$\ln(a)$ (95% CI)	$b$ (95% CI)	$R^2$	$c$ (95% CI)	$R^2$
Colorado	March 10–April 6	March 26	April 6	2	2671	1.28 (1.02–1.54)	0.24 (0.22–0.25)	0.973	30.89 (25.28–36.5)	0.695
Minnesota	March 19–April 8	March 28	April 8	7	912	2.02 (1.8–2.24)	0.19 (0.17–0.21)	0.965	9.993 (8.86–11.12)	0.865
Ohio	March 17–April 4	March 24	April 4	17	3340	2.94 (2.75–3.13)	0.23 (0.21–0.24)	0.98	38.23 (32.78–43.67)	0.803
Virginia	March 19–April 10	March 30	April 10	19	2165	2.77 (2.69–2.85)	0.178 (0.172–0.184)	0.994	23.31 (19.74–26.9)	0.775

Abbreviation: COVID-19, coronavirus disease 2019.

\* Fitting period consists of observed data from the first day of reporting up to and including the median effective date of the state’s stay-at-home order.

Figure. Projected vs Observed COVID-19 Hospitalizations Before and After Stay-at-Home Orders, March 10 Through April 28, 2020



Blue lines indicate observed cumulative hospitalizations (including those currently hospitalized and those discharged) up to each day; select values are displayed for clarity. Dashed red lines begin on the first day of available reporting by each state and are the best-fit exponential curves for cumulative hospitalizations for the fitting period: first day of reporting up to and including the median effective date (panel A:  $y = 3.5829 \exp(0.23599t)$ ,  $R^2 = 0.9734$ ; B:  $y = 7.521 \exp(0.1876t)$ ,  $R^2 = 0.96445$ ; C:  $y = 18.8482 \exp(0.2268t)$ ,  $R^2 = 0.9798$ ; D:  $y = 15.932 \exp(0.1397t)$ ,  $R^2 = 0.99444$ ). Shaded regions indicate the 95% prediction bands of the exponential growth curves. Because the median incubation period of coronavirus disease 2019 (COVID-19) was reported to be 4 to 5.1 days<sup>3,4</sup> and the median time from first symptom to hospitalization was found to be 7 days,<sup>5</sup> it was hypothesized that any association between stay-at-home orders and hospitalization rates would become evident after 12 days (median effective date).

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**Author Contributions:** Drs Sen and Karaca-Mandic had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.  
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**Acquisition, analysis, or interpretation of data:** All authors.  
**Drafting of the manuscript:** All authors.  
**Critical revision of the manuscript for important intellectual content:** All authors.  
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hospitalization to establish this date. Other factors that potentially decreased the rate of virus spread and subsequent hospitalizations include school closures, social distancing guidelines, and general pandemic awareness. In addition, economic insecurity and loss of health insurance during the pandemic may have also decreased hospital utilization. Limitations of the study include that these other factors could not be modeled in the analysis and that data on only 4 states were available.

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# COVID-19 Considerations for People with SUD

- High risk of co-morbidities that may increase severity of COVID-19
  - COPD, Cirrhosis, HIV
  - Smoking
- Overlap between symptoms of opioid withdrawal and COVID-19 infection
- Risk of drug overdose due to social distancing/isolation, drug supply disruption, reduced access to community-based naloxone distribution
- Increase in other substance use including alcohol
- Barriers to accessing treatment due to illness, quarantine, and financial resources for both patients and providers





# What Impact Has COVID-19 Had on Outpatient Visits?

April 23, 2020

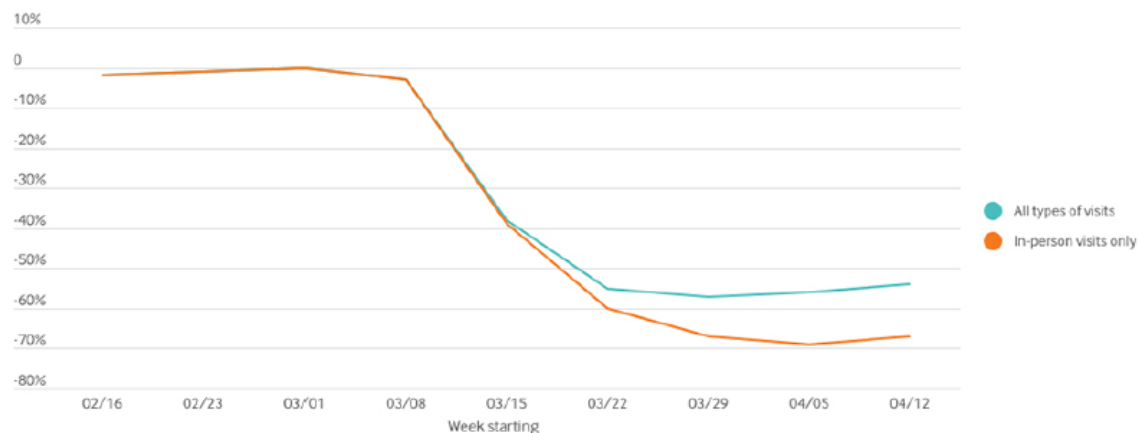
| [Ateev Mehrotra](#), [Michael Chernew](#), [David Linetsky](#), [Hilary Hatch](#), and [David Cutler](#)



**As the number of in-person visits dropped, telehealth visits increased. But the increase in telehealth visits only partially offset the drop in in-person visits.**

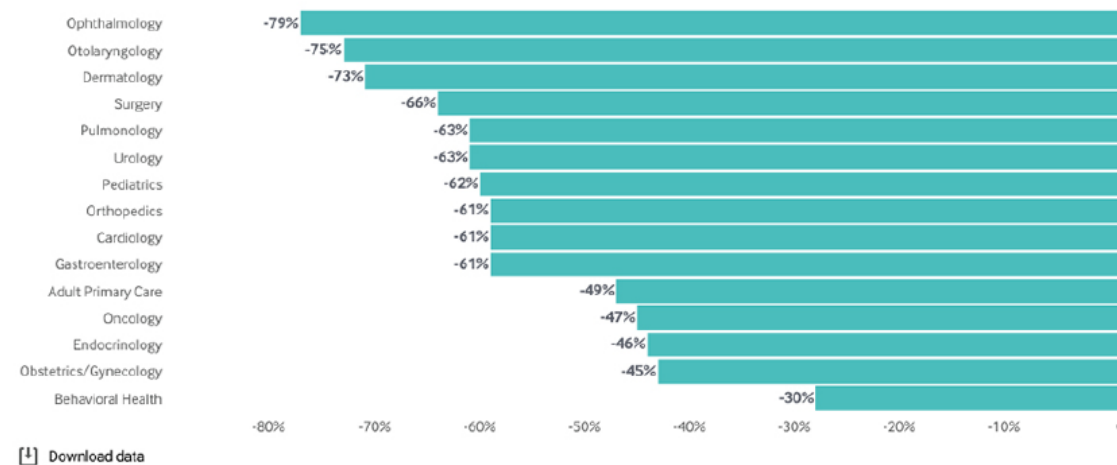
The decline among in-person visits is steeper than the decline among visits of any type (telemedicine and in-person).

Percent change in visits from baseline



**The decline in visits was generally larger among surgical and procedural specialties and smaller in other specialties such as adult primary care, obstetrics/gynecology, oncology, and behavioral health.**

Percent change in visits from baseline to week of April 5





# Changes in federal regulations

- **HIPAA - Enforcement discretion for telehealth** <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>
  - “The Office for Civil Rights will exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency. ”
- **42 CFR Part 2** - <https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf>
  - “We emphasize that, under the medical emergency exception, providers make their own determinations whether a bona fide medical emergency exists for purposes of providing needed treatment to patients.”
- **Ryan Haight Act** - <https://www.deadiversion.usdoj.gov/coronavirus.html>
  - “Accordingly, as of March 16, 2020, and continuing for as long as the Secretary’s designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:
    - The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
    - ~~The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and~~
  - March 31, 2020 guidance: DEA will allow waived physicians to initiate buprenorphine using telephonic (audio-only) communication
  - The practitioner is acting in accordance with applicable Federal and State laws.”

## Collision of the COVID-19 and Addiction Epidemics

Nora D. Volkow, MD

Coronavirus disease 2019 (COVID-19) is causing untold challenges to health care and wider social structures. Among the vulnerable populations are persons who smoke or vape, use opioids, or have a substance use disorder (SUD). Because of direct challenges to respiratory health, those with SUD may be especially susceptible to infection by the virus that causes COVID-19 and associated complications. And because of impediments to delivering care to this population, persons with SUD who develop COVID-19 may find it harder to get care. Those in recovery will also be uniquely challenged by social distancing measures.

Risk for severe COVID-19 and death escalates with older age but is also concentrated among those who are immunocompromised or have underlying health conditions, including diabetes, cancer, and heart and respiratory diseases. Many of the latter arise from smoking and thus may increase risk for death and illness among smokers (tobacco or cannabis). Data from the Chinese Center for Disease Control and Prevention have suggested that COVID-19 has a case fatality rate of 6.3% for individuals with chronic respiratory disease, compared with 2.3% overall (1). Comorbid chronic obstructive pulmonary disease, cardiovascular disease, and other respiratory diseases, which are more frequent among chronic smokers and persons with other SUDs, have been shown to worsen prognosis with other coronaviruses, including those causing severe acute respiratory syndrome and Middle East respiratory syndrome (2).

Persons whose lungs may be compromised from vaping nicotine or tetrahydrocannabinol (or even just flavorings) may also be at risk. The highly publicized lung illnesses from vaping, including “popcorn lung” and e-cigarette or vaping product use-associated lung injury, alert us to the potential for lung injury from vaping, which is on the rise especially in young persons. Preclinical studies show that e-cigarette aerosols can damage lung tissue, cause inflammation, and diminish the lungs’ ability to respond to infection (3).

Compromised lung function from COVID-19 could also put at risk those who have opioid use disorder (OUD) or methamphetamine and other psychostimulant use disorders. Chronic respiratory disease increases risk for fatal overdose in those who use opioids therapeutically (4). In addition, slowed breathing due to opioids causes hypoxemia, which can lead to cardiac, pulmonary, and brain complications (5) and, if severe, can result in overdoses and death. At least 2 million persons in the United States have OUD, and more than 10 million misuse opioids; these individuals may be at increased risk for the most adverse consequences of COVID-19. Methamphetamine is a highly toxic drug that causes pulmonary damage, pulmonary hyperten-

sion, and cardiomyopathy (6), and its use has markedly increased in the United States; clinicians should be alert to the possibility of increased risk for adverse COVID-19 outcomes in methamphetamine users.

Many risks of the current pandemic to persons with SUD are indirect. They arise from such factors as housing instability and incarceration, as well as reduced access to health care and recovery support services. A high percentage of individuals with SUD experience homelessness, and vice versa. Among countless other difficulties and risks faced by those who have housing instability, increased risk for disease transmission in homeless shelters is particularly important now. The

## Annals of Internal Medicine

## IDEAS AND OPINIONS

## When Epidemics Collide: Coronavirus Disease 2019 (COVID-19) and the Opioid Crisis

William C. Becker, MD, and David A. Fiellin, MD

With the coronavirus disease 2019 (COVID-19) pandemic projected to be the largest mass casualty event in U.S. history, large-scale efforts are under way to contain the spread through social distancing and to divert resources to acute care. Before the first COVID-19 case in the United States, a different epidemic—the opioid crisis—was taking the lives of 130 Americans per day (1). Given that infection epidemics disproportionately affect socially marginalized persons with medical and psychiatric comorbid conditions—characteristics of those with opioid use disorder (OUD)—we are gravely concerned that COVID-19 will increase already catastrophic opioid overdose rates. Besides the threat of infection to persons with OUD, there is serious risk that system-level gains in expanding access to medication for OUD, conducting critical research, and exacting legal reparations against opioid manufacturers will all reverse. We call for urgent action to counteract these risks.

Treatment systems need to facilitate uninterrupted access to the most effective medications for OUD treatment: methadone and buprenorphine (2). Regarding methadone, federal agencies relaxed requirements for physical examinations and allowed extended medication supply for stable patients (3). We need to rapidly expand methadone delivery via mobile teams (for example, repurposed syringe service programs) for quarantined patients. Opioid treatment programs—federally regulated facilities that primarily dispense methadone—should increase use of buprenorphine because of its safer pharmacologic properties and formulations that can be dosed thrice weekly and monthly. Federal agencies should leverage funds from a recent settlement about misuse of regulatory procedures by a buprenorphine manufacturer (4) to address financial barriers to buprenorphine provided through opioid treatment programs.

Buprenorphine prescribers should be allowed and encouraged to engage in all phases of care—evaluation, initiation of therapy, and monitoring—via telemedicine when appropriate. The Drug Enforcement Administration recently took a significant step by permitting teleprescribing of buprenorphine if 2-way audiovisual communication between the prescriber and the patient is in place, allowing for telephone-only communication when needed (5). Given that patients may not have adequate data access plans, we recommend that funding be allocated to support data plans for teleprescribing visits for patients initiating or continuing buprenorphine (and methadone) treatment. In-home initiation of buprenorphine is feasible and safe and is supported by new dose titration protocols that eliminate the need for opioid withdrawal (6).

We recommend several additional steps to ensure access to buprenorphine in preparation for shifts in prescribers’ work duties or sick leave due to COVID-19 and potential treatment disruptions as patients move in and out of hospitals. The federal government should temporarily remove limits on the number of patients an individual prescriber may treat concurrently. At present, clinicians are limited in the number of patients for whom they can treat concurrently in their first year. For the near future, these limits should be removed. In addition, we recommend that federal, state, and local governments be funded to form and support networks of experienced buprenorphine prescribers to address the needs of local patients and providers. For instance, the mentors from the federally funded Prescriber Clinical Support System, and those identified through primary care, addiction medicine, and addiction psychiatry societies, could be rapidly expanded and authorized to temporarily support clinicians and potentially prescribe for patients in their region if usual prescribers are unavailable. As more patients with OUD are admitted to hospitals, these networks would be available to provide remote consultative services to help reduce length of stay. To help reduce emergency department and hospital crowding, federal training requirements for buprenorphine should be eliminated to allow emergency medicine and hospitalist clinicians without waivers to write buprenorphine prescriptions at discharge to provide enough medication for patients to become engaged in outpatient treatment. Federal and state agencies should ensure that skilled-nursing facilities do not refuse patients receiving methadone or buprenorphine.

Beyond day-to-day OUD treatment, COVID-19 threatens to grind essential clinical research to a halt unless proactive steps are taken. During the past 2 years, Congress authorized approximately \$1 billion in the HEAL (Helping to End Addiction Long-term) initiative. Much of this work is just starting. In 2019, HEAL funded approximately 375 projects in 41 states, including 4 states as part of the HEALing Communities Study testing a “community-engaged intervention designed to increase the adoption of an integrated set of evidence-based practices delivered across health care, behavioral health, justice, and other community-based settings” (7). With virtually all research involving face-to-face contact stopping, these results will be delayed and study viability will be threatened. The effect of the COVID-19 pandemic on scientific validity will also need

## See also:

## Related articles

## Drug and Alcohol REVIEW



Drug and Alcohol Review (May 2020), 39, 301–304

DOI: 10.1111/dar.13074

## COMMENTARY

## Alcohol use in times of the COVID 19: Implications for monitoring and policy

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## Abstract

Based on a literature search undertaken to determine the impacts of past public health crises, and a systematic review of the effects of past economic crises on alcohol consumption, two main scenarios—with opposite predictions regarding the impact of the current COVID-19 pandemic on the level and patterns of alcohol consumption—are introduced. The first scenario predicts an increase in consumption for some populations, particularly men, due to distress experienced as a result of the pandemic. A second scenario predicts the opposite outcome, a lowered level of consumption, based on the decreased physical and financial availability of alcohol. With the current restrictions on alcohol availability, it is postulated that, for the immediate future, the predominant scenario will likely be the second, while the distress experienced in the first may become more relevant in the medium- and longer-term future. Monitoring consumption levels both during and after the COVID-19 pandemic will be necessary to better understand the effects of COVID-19 on different groups, as well as to distinguish them from those arising from existing alcohol control policies. [Rehm J, Kilian C, Ferreira-Borges C, Jernigan D, Monteiro M, Parry CDH, Sanchez ZM, Manthey J. Alcohol use in times of the COVID 19: Implications for monitoring and policy. *Drug Alcohol Rev* 2020;39:301–304]

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## Issue brief: Reports of increases in opioid-related overdose and other concerns during COVID pandemic

\*Updated May 25, 2020

As the COVID-19 global pandemic continues, so does the nation's opioid epidemic. The AMA is greatly concerned by an increasing number of reports from national, state and local media suggesting increases in opioid-related mortality—particularly from illicitly manufactured fentanyl and fentanyl analogs. More than 20 states have reported increases in opioid-related mortality as well as ongoing concerns for those with a mental illness or substance use disorder in counties and other areas within the state. See below for select national and state examples.

The AMA is pleased that the U.S. Substance Abuse and Mental Health Services Administration and U.S. Drug Enforcement Administration (DEA) have provided increased flexibility for providing buprenorphine and methadone to patients with opioid use disorder. The AMA is further pleased at increased flexibility provided by the DEA to help patients with pain obtain necessary medications.

There are four actions that must occur, however, to put these new policies into action and help reduce opioid-related harms.

- Governors must adopt the new SAMHSA and DEA rules and guidance in-full for the duration of the national emergency—this includes flexibility for evaluation and prescribing requirements using telemedicine;
- States must enact as part of their own Emergency Orders and other actions a complete removal of prior authorization, step therapy and other administrative barriers for medications used to treat opioid use disorder;
- States must remove existing barriers for patients with pain to obtain necessary medications. This includes removing arbitrary dose, quantity and refill restrictions on controlled substances; and
- States must enact, implement and support harm reduction strategies, including removing barriers to sterile needle and syringe services programs.

Read the full range of AMA recommendations for states to help patients with opioid use disorder and pain as well as how to further harm reduction efforts.

For more information, please contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, AMA Advocacy Resource Center, at [daniel.blaney-koen@ama-assn.org](mailto:daniel.blaney-koen@ama-assn.org) or (312) 464-4954.

### National reports

- The pandemic may fuel the next wave of the opioid crisis. <https://www.nationalgeographic.com/science/2020/04/coronavirus-pandemic-may-fuel-the-next-wave-of-the-opioid-crisis/> April 21, 2020

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### 23. Tennessee

- Opioid crisis sees impact of COVID-19 in Middle Tennessee. <https://www.wkrn.com/community/health/coronavirus/opioid-crisis-sees-impact-of-covid-19-in-middle-tennessee/> May 8, 2020

### 24. Texas

- WilCo sees spike in opioid overdose calls, counterfeit pills. <https://talk1370radio.com/articles/wilco-sees-spike-in-opioid-overdose-calls-counterfeit-pills> (Williamson County) April 17, 2020

### 25. Virginia

- Opioid Overdose Deaths Plunge in Virginia Counties After Influx of Naloxone. Harm reduction has worked, but causes for concern during pandemic remain.\* <https://www.directrelief.org/2020/05/opioid-overdose-deaths-plunge-in-virginia-counties-after-influx-of-naloxone/> May 24, 2020

### 26. Washington

- Seattle sees spike in fentanyl overdose deaths. <https://dailyhive.com/seattle/king-county-spike-overdose-deaths> April 24, 2020

### 27. West Virginia

- Police: Three people overdose on opioids at same time, same place in North Wheeling. <https://wtov9.com/news/local/police-three-people-overdose-on-opioids-at-same-time-same-place-in-north-wheeling> May 16, 2020

### 28. Wisconsin

- Public health alert issued in Dane County following suspected rise in opioid overdoses. <https://www.channel3000.com/public-health-alert-issued-in-dane-county-following-suspected-rise-in-opioid-overdoses/> April 7, 2020
- Fentanyl overdose deaths on the rise in Milwaukee County. <https://www.tmj4.com/news/local-news/fentanyl-overdose-deaths-on-the-rise-in-milwaukee-county> April 17, 2020
- Opioid crisis getting worse during COVID-19 pandemic, medical professionals say. (Madison) <https://www.nbc15.com/content/news/Opioid-crisis-getting-worse-during-COVID-19-pandemic-medical-professionals-say-569900351.html> April 23, 2020



## Letters

### RESEARCH LETTER

#### Psychological Distress and Loneliness Reported by US Adults in 2018 and April 2020

Coronavirus disease 2019 (COVID-19) introduced stressors to mental health, including loneliness stemming from social isolation, fear of contracting the disease, economic strain, and uncertainty about the future. We fielded a national survey measuring symptoms of psychological distress and loneliness among US adults in April 2020 and compared results with national data from 2018.

**Methods** | We fielded the Johns Hopkins COVID-19 Civic Life and Public Health Survey from April 7 to April 13, 2020, using NORC's AmeriSpeak Panel. AmeriSpeak is a probability-based panel designed to be representative of the US adult population. The panel is sourced from NORC's area probability sample and from a US Postal Service address-based sample covering 97% of US households.<sup>1</sup> The panel has a recruitment rate of 34% and includes approximately 35 000 members. The sample for the Johns Hopkins survey was drawn from this panel and the survey was administered online. NORC obtains informed consent prior to enrolling individuals in the panel. The Johns Hopkins Bloomberg School of Public Health institutional review board deemed this study not human participants research and waived informed consent.

We measured the prevalence of symptoms of serious psychological distress in the overall sample and among demographic subgroups using the Kessler 6 Psychological Distress Scale, with the validated measure of serious distress defined as a score of 13 or higher on the 0- to 24-point scale.<sup>2</sup> We also measured the proportion of respondents who reported that they always or often feel lonely in response to the item "How often do you feel lonely?" with response options always, often, sometimes, rarely, and never.

We compared the prevalence of symptoms of serious psychological distress in April 2020 with an identical measure from the 2018 National Health Interview Survey (NHIS), which used the Kessler 6 scale among 25 417 adults aged 18 years or older in household interviews. The 2018 NHIS response rate was 64.2%.<sup>3</sup>

For each measure, we calculated proportions and 95% CIs using Stata version 15 (StataCorp). The Johns Hopkins and NHIS survey data were analyzed separately. Analyses of both data sets incorporated survey sampling weights to generate nationally representative estimates.

**Results** | The survey response rate was 70.4%, with a final sample of 1468 adults aged 18 years or older.

In April 2020, 13.6% (95% CI, 11.1%-16.5%) of US adults reported symptoms of serious psychological distress, relative to 3.9% (95% CI, 3.6%-4.2%) in 2018 (Figure). Among the subgroups examined, in April 2020, symptoms of psychological

The corresponding prevalence estimates for these 3 groups in 2018 were 3.7% (95% CI, 3.0%-4.6%), 7.9% (95% CI, 7.1%-8.6%), and 4.4% (95% CI, 3.7%-5.4%), respectively. The lowest prevalence of serious psychological distress among the subgroups examined in April 2020 was observed in adults aged 55 years or older (7.3% [95% CI, 4.8%-10.9%]). In April 2020, 13.8% (95% CI, 11.4%-16.6%) of US adults reported that they always or often felt lonely.

**Discussion** | The prevalence of reported symptoms of psychological distress among US adults was higher in 2020 during the COVID-19 pandemic than in 2018. This finding builds on prior research documenting psychological distress among health care workers responding to COVID-19.<sup>4</sup>

The measure of serious psychological distress derived from the Kessler 6 scale has been shown to accurately predict serious mental illness,<sup>2</sup> suggesting acute distress during COVID-19 may transfer to longer-term psychiatric disorders. In April 2020, 13.8% of US adults reported that they always or often felt lonely. In comparison, a national survey using an identical measure of loneliness found that 11% of US adults reported always or often feeling lonely in April and May 2018.<sup>5</sup> Because loneliness increased only slightly from 2018 to 2020, other factors may be driving psychological distress during the COVID-19 pandemic.

The NORC AmeriSpeak panel used probability-based recruitment consistent with best-practice standards for survey research,<sup>6</sup> but results may be vulnerable to sampling biases. The degree to which US adults classified as essential workers during the COVID-19 pandemic were represented in the survey sample is unknown. While both surveys are designed to be nationally representative of US adults, the sampling and recruitment methods and mode of administration varied in the Johns Hopkins April 2020 and NHIS 2018 surveys. There is a potential for selection bias if individuals were more likely to respond to a survey about psychological distress in April 2020 vs 2018.

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**Author Contributions:** Dr McGinty had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Concept and design:** McGinty, Han, Barry.

**Acquisition, analysis, or interpretation of data:** All authors.

**Drafting of the manuscript:** McGinty.

**Critical revision of the manuscript for important intellectual content:** All authors.

**Statistical analysis:** McGinty, Presskreischer.

**Obtained funding:** McGinty, Han, Barry.

**Administrative, technical, or material support:** Barry.

**Supervision:** McGinty, Han, Barry.

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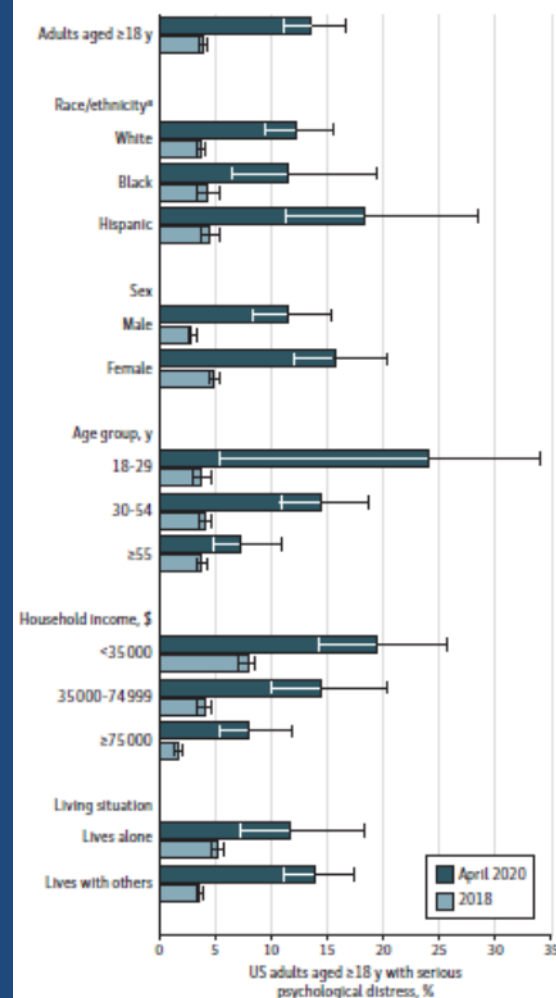
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Figure. Psychological Distress Among US Adults Aged 18 Years or Older Overall and by Subgroup, April 2020 vs 2018



April 2020 measures are from wave 1 of the Johns Hopkins COVID-19 Civic Life and Public Health Survey, fielded April 7-13, 2020 (N = 1468 adults aged ≥18 years). 2018 Measures of psychological distress are from the 2018 National Health Interview Survey (N = 25 417 adults aged ≥18 years). Psychological distress was measured using the Kessler 6 Psychological Distress Scale, with scores of 13 or higher indicating serious psychological distress. The error bars indicate 95% CIs.

\* Race/ethnicity was collected as part of the demographic profile in both the April 2020 Johns Hopkins survey and the 2018 National Health Interview Survey. In both surveys, the options were defined by the study investigators, and participants classified their own race/ethnicity.



RESEARCH LETTER

Prescription Fill Patterns for Commonly Used Drugs During the COVID-19 Pandemic in the United States

Conflicting information regarding the benefits of hydroxy-chloroquine/chloroquine and azithromycin in coronavirus disease 2019 (COVID-19) treatment and hypothetical concerns for drugs, such as angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs), have challenged care during the pandemic.<sup>1</sup> However, limited data are available about how prescription of these therapies has changed. The objective of this exploratory analysis was to evaluate prescription patterns of these therapies, along with other commonly used drugs for reference, in the United States during the COVID-19 pandemic. We hypothesized that the prescription of hydroxychloroquine/chloroquine and azithromy-

cin would exceed historical estimates while ACE inhibitor/ARB use would be reduced.

**Methods |** Trends in mean weekly prescriptions dispensed between February 16 and April 25, 2020, of hydroxychloroquine/chloroquine, azithromycin, and the top 10 drugs based on total claims in 2019, which included the most common ACE inhibitor (lisinopril) and ARB (losartan), were compared with mean weekly prescriptions dispensed from February 17 to April 27, 2019 (**Table**). We used all-payer US pharmacy data from 58 332 chain, independent, and mail-order pharmacies across 14 421 zip codes in 50 states, reflecting approximately 17 million deidentified claims.<sup>2</sup> Prescriptions of hydroxychloroquine/chloroquine were also examined based on fill quantity (<28 tablets, 28-60 tablets, or >60 tablets). Pharmacy claims were assigned weights to match prescription data from the Medical

Table. Estimates of Total Weekly Fills and Relative Percentage Change From 2019 Estimates of Commonly Prescribed Drugs, Azithromycin, and Hydroxychloroquine/Chloroquine\*

Drug	February 16-22	February 23-29	March 1-7	March 8-14	March 15-21	March 22-28	March 29-Apr 4	April 5-11	April 12-18	April 19-25
Amlodipine										
Change from 2019, % (95% CI)	3.9 (2.4 to 5.4)	9.1 (7.0 to 11.5)	13.2 (10.9 to 15.9)	19.4 (15.0 to 25.2)	32.3 (23.7 to 43.7)	4.3 (-2.3 to 13.3)	-3.7 (-9.3 to 3.6)	-7.4 (-13.4 to 0.1)	-8.0 (-14.2 to 0.2)	-9.2 (-15.5 to -3.3)
Weekly fill volume <sup>b</sup>	1 795 987	1 885 745	1 956 234	2 064 406	2 286 352	1 802 359	1 664 743	1 599 726	1 590 300	1 568 986
Amoxicillin										
Change from 2019, % (95% CI)	0.2 (-1.6 to 2.1)	-0.5 (-2.3 to 1.3)	-2.8 (-4.4 to -1.1)	-5.0 (-6.8 to -3.2)	-20.2 (-22.6 to -17.6)	-44.5 (-46.6 to -42.0)	-54.7 (-56.6 to -52.3)	-61.9 (-63.4 to -60.0)	-63.3 (-64.7 to -61.7)	-64.4 (-65.8 to -63.0)
Weekly fill volume <sup>b</sup>	750 589	745 429	728 587	711 556	597 551	415 937	339 287	285 352	275 002	266 455
Atorvastatin										
Change from 2019, % (95% CI)	1.4 (0.0 to 3.0)	7.0 (4.6 to 9.5)	11.2 (8.7 to 14.1)	17.0 (12.4 to 22.4)	30.9 (19.4 to 46.0)	4.7 (-5.2 to 18.1)	-5.3 (-11.9 to 2.2)	-8.1 (-14.8 to -0.2)	-8.0 (-15.0 to 0.2)	-9.1 (-16.0 to -0.9)
Weekly fill volume <sup>b</sup>	2 450 791	2 583 872	2 686 683	2 826 689	3 161 659	2 529 696	2 286 659	2 219 255	2 223 731	2 195 951
Azithromycin										
Change from 2019, % (95% CI)	1.3 (-0.7 to 3.6)	3.3 (1.4 to 5.6)	3.0 (0.9 to 5.0)	5.1 (3.2 to 7.3)	8.7 (5.7 to 12.3)	-12.0 (-14.6 to -8.7)	-31.5 (-34.0 to -28.2)	-47.9 (-49.8 to -45.5)	-57.6 (-59.0 to -56.0)	-62.7 (-63.8 to -61.3)
Weekly fill volume <sup>b</sup>	373 638	380 949	379 756	387 598	400 781	324 522	252 534	192 014	156 166	137 642
Gabapentin										
Change from 2019, % (95% CI)	-0.9 (-2.5 to 0.9)	3.6 (1.6 to 6.0)	6.5 (4.6 to 8.7)	7.8 (4.6 to 12.0)	15.0 (9.2 to 23.3)	-0.6 (-6.2 to 7.1)	-5.8 (-10.4 to 0.2)	-7.3 (-12.5 to -0.5)	-5.9 (-10.8 to 0.6)	-7.9 (-12.5 to -1.7)
Weekly fill volume <sup>b</sup>	1 189 617	1 242 901	1 278 137	1 293 476	1 379 772	1 192 865	1 130 251	1 111 808	1 129 336	1 105 475
Hydrocodone-acetaminophen										
Change from 2019, % (95% CI)	-0.3 (-2.2 to 1.6)	0.1 (-2.0 to 2.4)	4.0 (1.8 to 6.1)	1.5 (-0.5 to 3.5)	-5.0 (-7.1 to -2.9)	-20.0 (-22.4 to -17.8)	-23.1 (-25.5 to -20.6)	-23.4 (-25.9 to -20.9)	-22.0 (-24.6 to -19.4)	-21.8 (-24.6 to -19.1)
Weekly fill volume <sup>b</sup>	668 493	671 374	697 461	680 318	637 300	536 497	515 708	513 472	523 161	524 289
Hydroxychloroquine/chloroquine										
Change from 2019, % (95% CI)	4.2 (0.8 to 7.8)	8.7 (5.2 to 11.9)	14.6 (11.1 to 18.0)	30.9 (26.0 to 36.0)	214.1 (205.0 to 224.5)	70.3 (53.0 to 84.1)	16.1 (3.8 to 25.9)	15.9 (4.2 to 26.0)	14.6 (2.9 to 24.4)	23.9 (15.7 to 32.2)
Weekly fill volume <sup>b</sup>	121 865	127 059	134 008	153 119	367 297	199 157	135 746	135 528	133 972	144 921

(continued)

Table. Estimates of Total Weekly Fills and Relative Percentage Change From 2019 Estimates of Commonly Prescribed Drugs, Azithromycin, and Hydroxychloroquine/Chloroquine\* (continued)

Drug	February 16-22	February 23-29	March 1-7	March 8-14	March 15-21	March 22-28	March 29-Apr 4	April 5-11	April 12-18	April 19-25
Levothyroxine										
Change from 2019, % (95% CI)	-3.6 (-6.0 to -1.2)	1.7 (-1.8 to 6.2)	4.9 (1.2 to 9.3)	13.9 (7.5 to 22.0)	26.5 (15.4 to 40.5)	-4.2 (-12.5 to 5.7)	-13.4 (-20.1 to -5.9)	-17.2 (-23.9 to -9.7)	-18.4 (-25.6 to -10.0)	-20.0 (-26.8 to -11.8)
Weekly fill volume <sup>b</sup>	2 152 395	2 270 747	2 343 272	2 543 319	2 824 392	2 138 545	1 933 865	1 849 352	1 821 221	1 785 567
Lisinopril										
Change from 2019, % (95% CI)	-2.8 (-4.5 to -1.0)	1.3 (-0.9 to 4.0)	5.0 (2.6 to 7.7)	12.1 (8.0 to 17.4)	23.2 (15.1 to 33.8)	-3.1 (-9.5 to 4.9)	-11.4 (-17.0 to -4.6)	-14.6 (-20.3 to -7.7)	-14.2 (-19.8 to -7.4)	-15.3 (-21.4 to -7.7)
Weekly fill volume <sup>b</sup>	2 159 871	2 252 153	2 333 755	2 491 220	2 739 128	2 152 981	1 968 396	1 897 783	1 906 602	1 883 315
Losartan										
Change from 2019, % (95% CI)	10.9 (9.3 to 12.5)	16.5 (14.5 to 18.6)	22.4 (20.1 to 24.8)	32.1 (28.6 to 36.7)	48.8 (39.2 to 60.9)	16.4 (7.6 to 27.3)	4.8 (-0.4 to 11.5)	5.1 (-2.0 to 13.9)	4.4 (-0.6 to 10.5)	1.7 (-3.8 to 8.7)
Weekly fill volume <sup>b</sup>	1 352 577	1 419 968	1 492 463	1 610 414	1 813 521	1 419 037	1 278 113	1 281 056	1 273 222	1 240 067
Omeprazole										
Change from 2019, % (95% CI)	2.0 (-0.2 to 4.2)	5.4 (3.3 to 7.5)	8.8 (6.6 to 11.0)	11.9 (8.4 to 15.8)	18.8 (12.7 to 27.3)	-0.8 (-6.0 to 6.2)	-5.7 (-10.6 to 0.2)	-7.8 (-12.9 to -1.2)	-5.8 (-11.1 to 1.0)	-8.2 (-12.9 to -2.2)
Weekly fill volume <sup>b</sup>	1 215 299	1 256 402	1 296 361	1 333 007	1 416 179	1 182 500	1 123 370	1 099 150	1 122 857	1 093 923
Sertraline										
Change from 2019, % (95% CI)	2.8 (0.9 to 5.0)	5.8 (3.1 to 9.0)	8.9 (6.2 to 11.8)	16.2 (11.2 to 23.0)	26.2 (16.8 to 38.6)	2.2 (-5.3 to 12.2)	-5.0 (-12.0 to 3.7)	-4.5 (-11.2 to 4.0)	-6.1 (-12.4 to 2.2)	-8.4 (-14.9 to 0.2)
Weekly fill volume <sup>b</sup>	920 698	947 224	974 883	1 040 632	1 130 214	915 002	850 676	855 155	840 862	820 444

\* Volume of prescriptions during study period (February 16 to April 25, 2020) were compared with February 17 to April 27, 2019.

<sup>b</sup> Estimated absolute volume of national weekly fills in 2020.

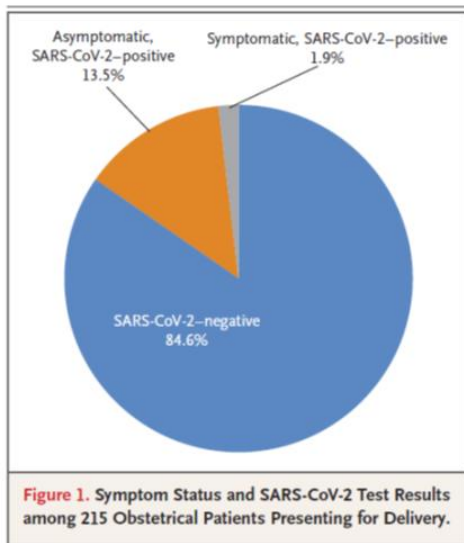
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## Universal Screening for SARS-CoV-2 in Women Admitted for Delivery

**TO THE EDITOR:** In recent weeks, Covid-19 has rapidly spread throughout New York City. The obstetrical population presents a unique challenge during this pandemic, since these patients

afebrile on admission. Nasopharyngeal swabs were obtained from 210 of the 211 women (99.5%) who did not have symptoms of Covid-19; of these women, 29 (13.7%) were positive for SARS-CoV-2.



**Figure 1.** Symptom Status and SARS-CoV-2 Test Results among 215 Obstetrical Patients Presenting for Delivery.

this prevalence has limited generalizability to geographic regions with lower rates of infection, it underscores the risk of Covid-19 among asymptomatic obstetrical patients. Moreover, the true prevalence of infection may be underreported because of false negative results of tests to detect SARS-CoV-2.<sup>3</sup>

The potential benefits of a universal testing approach include the ability to use Covid-19 status to determine hospital isolation practices and bed assignments, inform neonatal care, and guide the use of personal protective equipment. Access to such clinical data provides an important opportunity to protect mothers, babies, and health care teams during these challenging times.

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## Original Research

# Testing of Patients and Support Persons for Coronavirus Disease 2019 (COVID-19) Infection Before Scheduled Deliveries

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**OBJECTIVE:** To evaluate the rate of coronavirus disease 2019 (COVID-19) infection with the use of universal testing in our obstetric population presenting for scheduled deliveries, as well as the concordance or discordance rate among their support persons during the initial 2-week period of testing. Additionally, we assessed the utility of a screening tool in predicting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing results in our cohort.

**METHODS:** This was an observational study in which all women who were scheduled for a planned delivery within the Mount Sinai Health system from April 4 to April 15, 2020, were contacted and provided with an appointment for themselves as well as their support persons to undergo COVID-19 testing 1 day before their scheduled delivery. Both the patients and the support persons were administered a standardized screen specific for COVID-19 infection by telephone interview. Those support persons who screened positive were not permitted to attend the birth. All patients and screen-negative support persons underwent SARS-CoV-2 testing.

**RESULTS:** During the study period, 155 patients and 146 support persons underwent SARS-CoV-2 testing. The

prevalence of asymptomatic COVID-19 infection was 15.5% (CI 9.8–21.2%) and 9.6% (CI 4.8–14.4%) among patients and support persons, respectively. The rate of discordance among tested pairs was 7.5%. Among patients with COVID-19 infection, 58% of their support persons also had infection; in patients without infection, fewer than 3.0% of their support persons had infection.

**CONCLUSION:** We found that more than 15% of asymptomatic maternity patients tested positive for SARS-CoV-2 infection despite having screened negative with the use of a telephone screening tool. Additionally, 58% of their asymptomatic, screen-negative support persons also tested positive for SARS-CoV-2 infection. Alternatively, testing of the support persons of women who had tested negative for COVID-19 infection had a low yield for positive results. This has important implications for obstetric and newborn care practices as well as for health care professionals.

(Obstet Gynecol 2020;00:1–5)

DOI: 10.1097/AOG.0000000000003985

The coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus has been declared a pandemic by the World Health Organization as of March

### Box 1. Telephone Screening Tool

All patients must answer these questions.

1. Do you have a fever or feel hot?
2. Do you have a cough, shortness of breath, or a sore throat?
3. Are you vomiting, or do you have diarrhea?
4. Do you have a rash?



RESEARCH LETTER

Prevalence of SARS-CoV-2 Among Patients Admitted for Childbirth in Southern Connecticut

Developing an approach to care for pregnancy and childbirth during the coronavirus disease 2019 (COVID-19) crisis is a priority to (1) provide safe care to pregnant women and newborns; and (2) protect health care workers from infection. A study conducted in New York City reported a 13.5% prevalence of asymptomatic infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in women presenting for childbirth.<sup>1</sup> On March 30, 2020, an initially asymptomatic woman admitted to the Yale New Haven Health system developed cough and fever soon after childbirth; testing confirmed SARS-CoV-2 infection. This event prompted the development of a SARS-CoV-2 screening and testing program of patients presenting for childbirth; we report the prevalence detected in the first weeks of the program.

**Methods** | From April 2, 2020, to April 29, 2020, screening and testing of patients admitted for childbirth was initiated at 3 Yale New Haven Health hospitals in southern Connecticut. Screening consisted of questions related to travel, contacts, and symptoms of COVID-19. All patients without a prior diagnosis of COVID-19 underwent SARS-CoV-2 polymerase chain reaction (PCR) testing of nasopharyngeal swabs, with rapid testing available. Patients scheduled for cesarean birth were screened and tested at preoperative visits.

Hospital policies recommended universal mask use on clinical units by clinicians, patients, and support persons and limited each patient to 1 support person visitor for childbirth. For patients with symptoms of COVID-19, clinicians wore N95 respirators and appropriate personal protective equipment (PPE) until results returned, continuing use for patients with positive test results. For patients without symptoms of COVID-19, clinicians followed usual precautions including wearing masks. For the second stage of labor and cesarean or vaginal birth, clinicians wore full PPE and N95 respirators for patients without test results or with positive tests. Excluded from universal testing were patients already diagnosed with COVID-19 and patients not admitted for childbirth. The numbers of positive PCR tests in patients with and without symptoms of COVID-19 were assessed over time. This quality improvement project does not meet the definition of human subjects research; review by the institutional review board was not required.

**Results** | Seven hundred eighty-two patients presenting for childbirth were screened; 1.5% (12/782) were previously diagnosed with COVID-19. The remaining 770 patients were tested at admission (Table 1) and 30 of 770 (3.9%) tested positive for SARS-CoV-2 (Table 2). Twenty-two of the 30 who tested positive for SARS-CoV-2 (73.3%) were asymptomatic.

Table 1. Demographics and Characteristics of Patients Tested for SARS-CoV-2 on Admission for Childbirth<sup>a</sup>

Characteristics	SARS-CoV-2 PCR result	
	Positive (n = 30)	Negative (n = 740)
Age, y		
<30	14 (46.7)	199 (26.9)
30-34	10 (33.3)	310 (41.9)
≥35	6 (20.0)	231 (31.2)
Nulliparity	16 (53.3)	323 (43.7)
Site of hospital		
Greenwich	8 (26.7)	204 (27.6)
Bridgeport	11 (36.7)	129 (17.4)
New Haven	11 (36.7)	407 (55.0)
Gestation <37 weeks at birth	0	62 (8.4)
Cesarean delivery <sup>b</sup>	10 (33.3)	275 (37.2)
APGAR score		
<7 At 1 minute	0	40 (5.4)
<7 At 5 minutes	0	12 (1.6)
Neonatal birth weight, mean (SD), g	3370 (621)	3331 (568)
Neonatal SARS-CoV-2 positive test result <sup>c</sup>	0	

Abbreviations: COVID-19, coronavirus disease 2019; PCR, polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

<sup>a</sup> Data are expressed as No. (%) of participants unless otherwise indicated. Excludes patients diagnosed with COVID-19 prior to admission, including those considered recovered (defined as ≥14 days from onset of symptoms and ≥72 hours afebrile).

<sup>b</sup> Mode of birth was determined by routine obstetric indications.

<sup>c</sup> Neonatal testing by PCR of nasopharyngeal swabs was performed at 24 hours of age.

The overall prevalence of positive test results among asymptomatic patients was 2.9% (22/756). Prevalence of positive test results among asymptomatic patients increased from 0.6% (2/355) to 5% (20/401) from the first 2 weeks (April 2-15, 2020) to the second 2 weeks (April 16-29, 2020), though the prevalence of symptomatic patients who tested positive in the total population admitted for childbirth decreased from 1.4% (5/365) to 0.7% (3/405) (Table 2). Fifty-seven percent (8/14) of patients with symptoms tested positive. No asymptomatic patients who tested negative developed symptoms or required further testing. No health care workers on the obstetric units were removed from work due to SARS-CoV-2 exposure or disease from transmission from a known or possible contact with a patient.

**Discussion** | These findings suggest a low (<3%) prevalence of positive SARS-CoV-2 test results among asymptomatic patients in a pregnant population outside of the highly endemic region of New York City. During this time period, these hospitals, with approximately 2200 licensed beds, experienced a peak (April 21, 2020) of 759 patients admitted for COVID-19,

Table 2. SARS-CoV-2 Test Results for Patients Tested at Admission for Childbirth, Stratified by Symptoms<sup>a</sup>

Screening characteristic	SARS-CoV-2 PCR result	Patients screened, No. (%) <sup>b</sup>		
		April 2-15, 2020 (n = 365)	April 16-29, 2020 (n = 405)	Total (n = 770)
Asymptomatic	Positive	2 (0.5)	20 (4.9)	22 (2.9)
	Negative	353 (96.7)	381 (94.1)	734 (95.3)
Symptomatic <sup>c</sup>	Positive	5 (1.4)	3 (0.7)	8 (1.0)
	Negative	5 (1.4)	1 (0.2)	6 (0.8)

Abbreviations: COVID-19, coronavirus disease 2019; PCR, polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

<sup>a</sup> Excludes patients diagnosed with COVID-19 prior to admission, including those considered recovered (defined as ≥14 days from onset of symptoms and ≥72 hours afebrile).

<sup>b</sup> Percentage is expressed as percentage of total patients tested during the time period.

<sup>c</sup> Signs and symptoms of COVID-19 in patients with positive SARS-CoV-2 test results were mild in 7 patients, including fever, headache, rhinorrhea, sore throat, myalgias, congestion, cough, anosmia/ageusia. One patient had severe symptoms, including fever, myalgias, malaise, congestion, and shortness of breath. No mildly symptomatic patients developed COVID-19-related complications. The severely symptomatic patient recovered from respiratory insufficiency with critical care and oxygen support via nonbreather mask.

and among US states, Connecticut had the 3rd highest death rate per capita from COVID-19, indicating a substantially affected region.<sup>2</sup> The increasing prevalence of positive SARS-CoV-2 test results in the asymptomatic population, while the prevalence of symptomatic infections decreased, may indicate that universal testing identifies patients in a convalescent period, in addition to those with subclinical active infection. Although performed in mixed community and academic hospital settings, limitations of the findings include a short duration and a single geographic region.

Approaches to care that balance screening and testing of patients combined with a rationalized approach to use of PPE should be considered for obstetric units.

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**Concept and design:** Campbell, Illuzzi, Sussman, Lipkind, Pettker.

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**Drafting of the manuscript:** Campbell, Illuzzi, Lipkind, Pettker.

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**Administrative, technical, or material support:** Tornatore, Pettker.

**Supervision:** Lawrence, Lipkind, Pettker.

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Kara Keough Bosworth shares the heart-wrenching story of her newborn son's death

CULTURE → PARENTING — May 11, 2020

## 'Real Housewives' star Kara Keough Bosworth opens up about the heartbreaking loss of her newborn son



By Lesley Messer



Video by Faith Bernstein

Over the past month, "Real Housewives of Orange County" star Kara Keough Bosworth has been keeping track of the milestones her son would have hit had he not died April 12, six days after he was born. She wonders what life would look like. What would he be doing?

McCoy Casey Bosworth experienced shoulder dystocia and a compressed umbilical cord during his birth, and days later, his parents received the prognosis they feared most: he'd suffered severe brain damage and was unlikely to recover.

"I've been lucky to hear from parents that are on the other side of it, or as far on the other side as you can be, and they say it gets better," Bosworth told "Good Morning America" in her first interview since the tragedy. "They say eventually the waves of grief don't feel like they're knocking you over every day, and that you have to just get through it -- but that you aren't alone."

"We had a strong son and he fought every second of his life," added her husband, former professional football player Kyle Bosworth. "Now we've got to figure out how to make his life meaningful."

### Inside the 'Olympic effort' to deliver her baby

Bosworth, 31, wanted her second pregnancy to be different than the one she had with her 4-year-old daughter, Decker. For starters, she and her husband, 33, opted not to find out the baby's sex ahead of time, and picked a name that would work no matter what: McCoy Casey.

"If it was a girl, we were gonna call her Mickey and a boy, we were gonna call him Mack," Bosworth, who works in content marketing, said. "We were all joking, 'Maybe when you're big someday, you'll be like, 'Mack Truck,' and that'll be a sports nickname.'" Kyle, who co-owns a real estate firm, came up with Casey, which incorporates the letters of his and Bosworth's siblings' names.

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# COVID-19 Considerations for Pregnant People

- There appears to be nothing pregnancy specific for COVID19
  - Maternal risk does not seem greater than general population (this is not H1N1)
  - Fetal/newborn risk does not seem greater (this is not Zika)
  - Not transmitted in breast milk
- Health Care Provider Safety – limited PPE and staffing
  - Limited to know other people in delivery room – lack of support for people in labor
  - *People with OUD may need more support*
- The biggest risk is the unknown
  - Maternal/newborn separation following delivery
  - Limited “rooming in” in NICUs with restrictions on number of transits per day
  - *People with OUD may feel less autonomy in resisting – and may suffer sequelae of separation more*

# COVID-19 General Response(s)

- Primary Response:
  - Provision of continuing care via (primarily) remote/tele services
- Under-emphasized:
  - Considerations for people with untreated addiction
  - Providers need to see new patients (either virtually or in-person)
- Lacking attention to “Special Populations”:
  - Pregnant people – for whom some in-person visits are essential (ie for prenatal care)
  - People with SUD – how they are experiencing the pandemic, social isolation, the in-person clinic experience
- Public Health/Public Policy: Balance staff safety and support of remote services with person-centered care



## JAMA Insights

## Caring for Women Who Are Planning a Pregnancy, Pregnant, or Postpartum During the COVID-19 Pandemic

Sonja A. Rasmussen, MD, MS; Denise J. Jamieson, MD, MPH

Since its recognition in China in December 2019, coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has rapidly spread throughout the world and become a pandemic. Although considerable data on COVID-19 are available, much remains to be learned about its effects on pregnant women and newborns.

No data are currently available to assess whether pregnant women are more susceptible to COVID-19. Pregnant women are at risk for severe disease associated with other respiratory illnesses (eg, 2009 H1N1 influenza),<sup>1</sup> but thus far, pregnant women with COVID-19 do not appear to be at increased risk for severe disease compared with the general population. Data from China showed that among 147 pregnant women, 8% had severe disease and 1% had critical illness, which are lower rates than observed in the nonpregnant population (14% with severe disease and 6% with critical illness).<sup>2</sup> Case series from China consisting primarily of women with third-trimester infection have shown that clinical findings in pregnant women are similar to those seen in the general population.<sup>1</sup> Conversely, a small Swedish study reported that pregnant and postpartum women with COVID-19 were 5 times more likely to be admitted to an intensive care unit compared with nonpregnant women of similar age.<sup>3</sup>

Data on pregnant women with COVID-19 in the US are beginning to accumulate. For example, a recent report included 43 pregnant women with COVID-19 who presented for care at 2 hospitals in New York City.<sup>4</sup> Although this case series did not include a nonpregnant control group, the proportion of pregnant women with severe disease was similar to that described in nonpregnant adults with COVID-19.<sup>4</sup> More information is needed about the effect of pregnancy and comorbidities to understand how they affect clinical outcomes of COVID-19. The US experience might differ from other countries because of the high frequency of comorbidities among pregnant women in the US.

The effects of COVID-19 during pregnancy on the neonate are not well understood. Nearly all infections reported from China were during the third or late-second trimester, so whether first-trimester SARS-CoV-2 infection might cause birth defects or pregnancy loss is unknown. Some newborns born to mothers with COVID-19 during pregnancy were born preterm or of low birth weight, but whether these outcomes were COVID-19-related is unclear. SARS-CoV-2 transmission from a mother to her newborn could occur prenatally, perinatally, or postnatally. In most newborns tested after birth, results have been negative for SARS-CoV-2.<sup>1</sup> However, symptomatic newborns born to mothers with COVID-19 have been reported to have SARS-CoV-2 infection at a few days of life<sup>5</sup>; whether this was due to prenatal, perinatal, or postnatal transmission is unknown. Recently, a probable case of congenital infection was reported in a newborn born to a woman with familial neutropenia who was diagnosed with COVID-19 before delivery. A neonatal nasopharyngeal swab collected on the day of birth prior to skin-to-skin maternal contact was positive.<sup>6</sup> The presence of IgM and IgG antibodies in 3 infants born to mothers with COVID-19 during pregnancy was recently reported.<sup>7</sup> IgG antibodies

freely cross the placenta; however, IgM antibodies do not typically cross the placenta, suggesting the possibility of prenatal transmission of SARS-CoV-2. However, these studies do not provide definitive evidence for intrauterine transmission because cross-reactivity and false-positive IgM test results can occur.<sup>7</sup> Whether transmission can occur through breastfeeding is unknown. SARS-CoV-2 RNA has been detected in breastmilk samples from a single woman with COVID-19, and her infant tested positive for SARS-CoV-2, but whether the infant was infected through breastfeeding is unclear.<sup>8</sup> Given the benefits of breast milk, when feasible, breast milk should be fed to infants regardless of maternal COVID-19 status.

Based on experiences with other infections (eg, influenza), adverse effects on the fetus or newborn related to prenatal infection might occur even without intrauterine transmission. For example, severe maternal illness with influenza requiring intensive care unit admission was associated with increased risks for preterm birth, low birth weight, and low Apgar scores.<sup>9</sup> Whether an increased risk for adverse outcomes among newborns born to women with COVID-19 will be seen is unknown.

Given the limited data, recommendations for caring for women who are planning a pregnancy, pregnant, or have given birth during the COVID-19 pandemic are based on expert opinion. Women planning a pregnancy in the time of COVID-19 might ask whether they should delay pregnancy until after the pandemic. Based on limited data, there does not seem to be a compelling reason to recommend delaying pregnancy. For women who are pregnant, the primary recommendation is to avoid becoming infected with SARS-CoV-2 through hygiene and social distancing measures. Early recognition of COVID-19 in a pregnant patient admitted to a labor and delivery unit is necessary so appropriate infection control practices can be instituted. Given that some women with COVID-19 might be asymptomatic or presymptomatic, health care facilities may consider polymerase chain reaction testing for SARS-CoV-2 at the time of admission.

Guidelines for the care of pregnant women known or suspected to have COVID-19 admitted for delivery have been developed by the Centers for Disease Control and Prevention (CDC) and several professional organizations (Box). On presentation, a mask should be placed on the woman and she should be isolated in a single-patient room with the door closed, with an airborne isolation room used for aerosol-generating procedures. Clinical care of a pregnant woman with COVID-19 should be based on illness severity; diagnostic measures and treatments should not be withheld based on pregnancy status. Given the risks of maternal respiratory depression, consideration should be given to limiting the use of magnesium sulfate for seizure prophylaxis and fetal neuroprotection. Given concerns about potential harm from corticosteroid use in patients with COVID-19, antenatal corticosteroid use for fetal maturation should be carefully considered and should depend on the gestational age. Early epidural analgesia should be considered to mitigate the risks associated with general anesthesia in the setting of an urgent cesarean delivery.

## Box. Recommendations for Care of Pregnant Women Confirmed or Suspected to Have Coronavirus Disease 2019 (COVID-19)

## Recommendations

- Place a mask on the patient on presentation and isolate in a single-person room with the door closed. Airborne isolation rooms should be used for aerosolizing procedures (ACOG, CDC, SMFM, SOAP).
- Consider separating patients with COVID-19 in one area of the obstetric unit and using a designated team of trained clinicians in these areas (SMFM, SOAP).
- Weigh benefits and risks of magnesium sulfate for fetal neuroprotection or for preeclampsia/intrapartum seizure prophylaxis given potential maternal respiratory depression (SMFM, SOAP).
- Consider adjusting antenatal corticosteroid use for fetal maturation, given the risk of worsening patient outcomes with corticosteroid use in patients with COVID-19 (eg, offer antenatal steroids for patients <34 weeks' gestation, weigh risks and benefits and individualize decisions for ≥34 weeks' gestation) (ACOG, SMFM, SOAP).
- Consider early epidural analgesia to mitigate the risks associated with general anesthesia in the setting of an urgent cesarean delivery (SMFM, SOAP).
- Do not alter delivery timing or mode (eg, cesarean delivery, operative vaginal delivery) due to patients' COVID-19 infection status. However, for women with COVID-19 in the third trimester, it may be reasonable to attempt to postpone delivery to decrease risk of neonatal transmission (ACOG).
- Consider temporary separation of mothers with confirmed COVID-19 from their newborns (ACOG, AAP, CDC).
- Determination of whether to temporarily separate a mother with known or suspected COVID-19 should be made on a case-by-case basis, using shared decision-making (ACOG, CDC).

- If temporary separation is chosen, mothers who intend to breastfeed should practice hand and breast hygiene and express their milk. Expressed milk can be fed to the newborn by a healthy caregiver (ACOG, AAP, CDC, SMFM, SOAP).
- If separation is not chosen, use other measures to reduce risk of infection, such as physical barriers and face mask use by the mother (AAP, CDC).
- Mothers who choose to feed at the breast should wear a face mask and practice hand and breast hygiene before each feeding (AAP, ACOG, CDC, SMFM, SOAP).
- Newborns born to mothers with confirmed COVID-19 at the time of delivery should be considered to have suspected COVID-19 and be isolated from healthy newborns (AAP, ACOG, CDC).
- Newborns born to mothers with confirmed or suspected COVID-19 at the time of delivery should be tested 24 hours after birth for SARS-CoV-2 and, if negative, again at approximately 48 hours if testing capacity is available (AAP, CDC).

## Professional Organization Resources

American Academy of Pediatrics (AAP) [initial guidance](#) and [FAQs](#)

American College of Obstetricians and Gynecologists (ACOG) [practice advisory](#) and [FAQs](#)

Centers for Disease Control and Prevention (CDC)

Society for Maternal-Fetal Medicine (SMFM) and Society for Obstetric Anesthesia and Perinatology (SOAP)

# COVID19 Public Policy and Public Health Response

- Federal (and State) regulations – eased in support of telehealth services
- Addiction Providers: decrease in volume (due to extended prescriptions, decreased hours and etc) leads to decrease income
- Prenatal Care Providers: slight decrease in volume (due to spaced out visits) with no change in clinic income (due to bundled payment)
- What about co-located services? The standard of care in addiction treatment during pregnancy?
- Increased attention to racial inequities in health (COVID-19 and Birth)



Coronavirus in Illinois

## In Chicago, 70% of COVID-19 Deaths Are Black

By Elliott Ramos, Maria Inés Zamudio

April 5, 10:25 AM EDT



Patricia Frieson (seated on the bottom right) was the first person to die from COVID-19 in Illinois. Her sister, Wanda Bailey (standing right), died in the weeks following. Courtesy of the family of Patricia Frieson

The COVID-19 virus is killing black residents in Cook County at disproportionately high rates, according to early data analyzed by WBEZ.

While black residents make up only 23% of the population in the county, they account for 58% of the COVID-19 deaths. And half of the deceased lived in Chicago, according to data from the Cook County Medical Examiner's office.

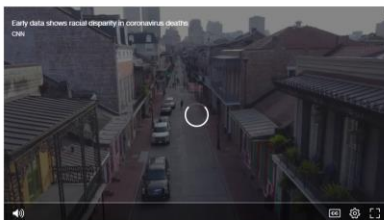


## The coronavirus pandemic is hitting black and brown Americans especially hard on all fronts



By Harneet Kaur, CNN

Updated 8:43 PM ET, Fri May 8, 2020



(CNN) — At first, the coronavirus pandemic was called the great equalizer.

It seemed to be affecting people of all races, backgrounds and income levels, from Hollywood actors to NBA players to low-wage service workers.

But as more data becomes available, one thing is clear: Covid-19 has only magnified the systemic inequalities that persist in the United States. And nonwhite Americans, especially African Americans, have been hit hard on nearly every front.

Though the available data paint a grim picture, the numbers are incomplete. Much of the state and federal data on Covid-19 cases and deaths are preliminary, while race and ethnicity information isn't even available for tens of thousands of cases. Advocacy groups have



Data Viz | Health | Demographics

## THE COLOR OF CORONAVIRUS: COVID-19 DEATHS BY RACE AND ETHNICITY IN THE U.S.



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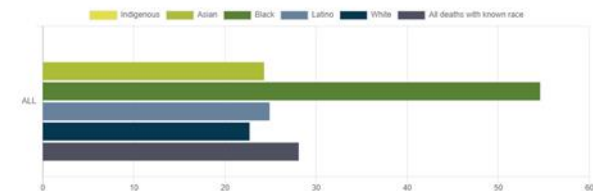


### SEARCH BY STATE

(Use Shift or Ctrl to select more than one state.)

 SEARCH

### COVID-19 DEATHS PER 100,000 PEOPLE OF EACH GROUP, THROUGH MAY 26, 2020



\* Includes data from Washington, D.C., and the 48 states of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington and Wisconsin. States employ varying collection methods regarding ethnicity data. Denominator is built from data aggregated from each state, aligned with their method. Comparable rates could not be calculated for Indigenous people, due to so few states reporting data.

## SPECIAL ARTICLE

# Hospitalization and Mortality among Black Patients and White Patients with Covid-19

Eboni G. Price-Haywood, M.D., M.P.H., Jeffrey Burton, Ph.D., Daniel Fort, Ph.D., and Leonardo Seoane, M.D.

## ABSTRACT

## BACKGROUND

Many reports on coronavirus disease 2019 (Covid-19) have highlighted age- and sex-related differences in health outcomes. More information is needed about racial and ethnic differences in outcomes from Covid-19.

## METHODS

In this retrospective cohort study, we analyzed data from patients seen within an integrated-delivery health system (Ochsner Health) in Louisiana between March 1 and April 11, 2020, who tested positive for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, the virus that causes Covid-19) on qualitative polymerase-chain-reaction assay. The Ochsner Health population is 31% black non-Hispanic and 65% white non-Hispanic. The primary outcomes were hospitalization and in-hospital death.

## RESULTS

A total of 3626 patients tested positive, of whom 145 were excluded (84 had missing data on race or ethnic group, 9 were Hispanic, and 52 were Asian or of another race or ethnic group). Of the 3481 Covid-19–positive patients included in our analyses, 60.0% were female, 70.4% were black non-Hispanic, and 29.6% were white non-Hispanic. Black patients had higher prevalences of obesity, diabetes, hypertension, and chronic kidney disease than white patients. A total of 39.7% of Covid-19–positive patients (1382 patients) were hospitalized, 76.9% of whom were black. In multivariable analyses, black race, increasing age, a higher score on the Charlson Comorbidity Index (indicating a greater burden of illness), public insurance (Medicare or Medicaid), residence in a low-income area, and obesity were associated with increased odds of hospital admission. Among the 326 patients who died from Covid-19, 70.6% were black. In adjusted time-to-event analyses, variables that were associated with higher in-hospital mortality were increasing age and presentation with an elevated respiratory rate; elevated levels of venous lactate, creatinine, or procalcitonin; or low platelet or lymphocyte counts. However, black race was not independently associated with higher mortality (hazard ratio for death vs. white race, 0.89; 95% confidence interval, 0.68 to 1.17).

## CONCLUSIONS

In a large cohort in Louisiana, 76.9% of the patients who were hospitalized with Covid-19 and 70.6% of those who died were black, whereas blacks comprise only 31% of the Ochsner Health population. Black race was not associated with higher in-hospital mortality than white race, after adjustment for differences in socio-demographic and clinical characteristics on admission.

**Table 1. (Continued)**

Characteristic	White Non-Hispanic (N=1030)	Black Non-Hispanic (N=2451)
Location of testing — no. (%)		
Primary care	222 (21.6)	337 (13.7)
Urgent care	196 (19.0)	215 (8.8)
Emergency department	391 (38.0)	1601 (65.3)
Inpatient	27 (2.6)	77 (3.1)
Other or unknown service area	194 (18.8)	221 (9.0)

**Table 2. Clinical Characteristics of 1382 Covid-19–Positive Patients Hospitalized between March 1 and April 11, 2020.\***

Characteristic	White Non-Hispanic (N=319)	Black Non-Hispanic (N=1063)
Age — yr	69.2±16.6	60.5±14.8
Female sex — no. (%)	127 (39.8)	578 (54.4)
Charlson Comorbidity Index score	1.0±1.8	1.3±2.2
Insurance — no. (%)		
Commercial	89 (27.9)	417 (39.2)
Medicare	178 (55.8)	458 (43.1)
Medicaid	18 (5.6)	124 (11.7)
Self-pay or other	34 (10.7)	64 (6.0)
Residence in low-income area — no. (%)	108 (33.9)	643 (60.5)

## The COVID Racial Data Tracker

About Racial Data Dashboard Complete Dataset (CSV)

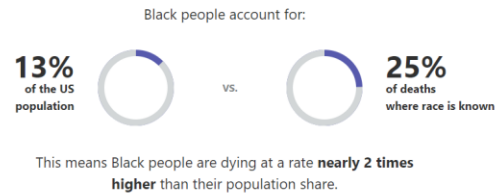
**COVID-19 is affecting people of color the most. We're tracking the data in real time.**

The COVID Racial Data Tracker is a collaboration between the COVID Tracking Project and the Antiracist Research & Policy Center. Together, we're gathering the most complete race and ethnicity data on COVID-19 in the United States.



Julia Leduc / COVID Tracking Project

**We've lost at least 20,399 Black lives to COVID-19 to date.**



**We've asked every state to report complete race and ethnicity data. Our Racial Data Dashboard has the latest.**

States and territories reporting race and ethnicity data

**48 states/territories**  
Reporting positive cases

**42 states/territories**  
Reporting deaths

[See the dashboard →](#)

[Get the complete dataset \(CSV\) →](#)

[Learn more about the tracker →](#)

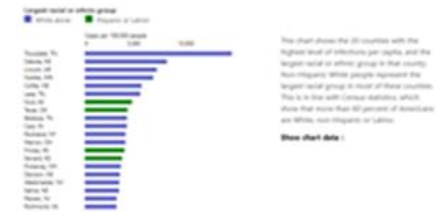
<https://covidtracking.com/race>

### Tracking inequity at the county level

State-level statistics tell part of the story, but many US states are also deeply segregated—meaning different counties in the same state can have vastly different breakdowns by race and ethnicity.

Race and ethnicity data for COVID cases isn't widely available at the county level, so we're using two numbers we do have: the latest infection and death rates for each county, from a New York Times dataset, paired with the largest racial or ethnic group in that county, based on the Census Bureau's 2018 ACS 5-Year estimates. The results are staggering.

#### Counties with the 25 highest infection rates



#### Counties with the 25 highest death rates



BLACK MATERNAL HEALTH

## Covid-19 Restrictions on Birth & Breastfeeding: Disproportionately Harming Black and Native Women

By: Kimberly Seals Allers | March 27, 2020



*Observations*  
| Opinion

### COVID-19 Is No Reason to Abandon Pregnant People

New rules prohibiting spouses or doulas during labor and delivery in many New York City hospitals are putting vulnerable populations at greater risk

By Monica R. McLemore on March 26, 2020



**National Advocates for Pregnant Women**

#### **What We Can Learn From Hospital Restrictions on Birth Support During the Coronavirus Pandemic**

The coronavirus pandemic, and our country's lack of preparedness for it, give us an opportunity to make important observations and learn (or relearn) key lessons. Foundational issues including severe income inequality, lack of a national health care system, and corporatization of public goods and services are being exposed during this pandemic. Also exposed are the Trump Administration's totally inadequate, often misleading and counterproductive responses to the coronavirus that have put all of us at risk.

For example, as Dr. Anne-Marie Slaughter explained in a [New York Times op-ed](#), South Korea mobilized health care companies to make coronavirus tests in late January, when the country had only four cases. Soon, 10,000 Koreans a day were being tested, and now new infections are dropping. The first cases in the United States were identified in January, too, and yet we still don't have enough tests.



COVID19 Pregnancy and SUD:  
Opportunities for Positive Practice Change  
But also Increasing Latitude of Harm

# Home- versus office-based Observed versus unobserved BUP inductions

- Home-based unobserved BUP induction and office-based observed induction are equally effective (Home induction not inferior)
- In-person is not essential to initiate BUP for OUD
- COVID-19 Response: can initiate via telephone (in addition to HIPAA-approved telehealth platforms)
- Hence pandemic response is not inferior care

Regula

Home- versus office-based  
for opioid-dep

Nancy L. Sohler, (Ph.D., M.P.H.)<sup>a,b,c,\*</sup>, Xuan Li, (Ph.D., M.P.H.)<sup>a,b,c,\*</sup>, Galit Sacajiu, (M.D., M.P.H.)<sup>c,d</sup>, Susan Whitley, (M.D.)<sup>c</sup>, Chinazo

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Regular article

A comparison of buprenorphine induction strategies: Patient-centered home-based inductions versus standard-of-care office-based inductions

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Abstract

Although novel buprenorphine induction strategies are emerging, they have been inadequately studied. To examine our newly developed patient-centered home-based inductions, we conducted a subgroup analysis of 79 opioid-dependent individuals who had buprenorphine inductions at an urban community health center. Participants chose their induction strategy. Standard-of-care office-based inductions were physician driven, with multiple assessments, and observed, and the patient-centered home-based inductions emphasized patient self-management and included a “kit” for induction at home. We conducted interviews and extracted medical records. Using mixed nonlinear models, we examined associations between induction strategy and opioid use and any drug use. Compared with those with standard-of-care office-based inductions, participants with patient-centered home-based inductions had no significant differences in opioid use (adjusted odds ratio [AOR] = 0.63, 95% confidence interval [CI] = 0.13–2.97) but greater reductions in any drug use (AOR = 0.05, 95% CI = 0.01–0.37). Taking into account the limitations of our observational cohort study design, we conclude that participants with patient-centered home-based inductions had similar reductions in opioid use and greater reductions in any drug use than those with standard-of-care office-based inductions. It is essential that new induction strategies be based on existing models or theories and be well studied. © 2011 Elsevier Inc. All rights reserved.

**Keywords:** Buprenorphine; Buprenorphine induction; Opioid; Opioid addiction treatment; Drug use; Primary care

Abstract

Recent legislation permits the treatment of opioid-dependent patients with the development of new treatment models for opioid dependence. We examined whether patients who had home-based inductions achieved reductions in opioid use compared with those who had office-based inductions in a study of 115 opioid-dependent patients treated in an office-based group versus 40 (78.4%) in home-based inductions. We examined whether patients who had home-based inductions achieved reductions in opioid use compared with those who had office-based inductions in a study of 115 opioid-dependent patients treated in an office-based group versus 40 (78.4%) in home-based inductions. We examined whether patients who had home-based inductions achieved reductions in opioid use compared with those who had office-based inductions in a study of 115 opioid-dependent patients treated in an office-based group versus 40 (78.4%) in home-based inductions.

**Keywords:** Buprenorphine treatment; Buprenorphine induction; Opioid dependence

1. Introduction

New legislation permits buprenorphine, a partial opioid agonist, to be used for the treatment of opioid dependence in the primary care setting (Drug Addiction Treatment Act, 2000). This provides opportunities to begin to develop and implement new treatment approaches for addiction care more generally. The Chronic Care Model (CCM), designed to improve long-term care for patients with chronic diseases (Wagner, 1998; Wagner et al., 2001), has great potential to

1. Introduction

Despite increasing rates of opioid dependence in the United States, opioid dependence remains severely undertreated (Cicero, Inciardi, & Munoz, 2005; Substance Abuse and Mental Health Services Administration [SAMHSA], 2008a, 2008b, 2009; Sung, Richter, Vaughan, Johnson, & Thom, 2005). To address this, federal legislation was enacted, which allows for opioid addiction treatment with buprenorphine to occur outside drug treatment programs.

Buprenorphine treatment is associated with positive health outcomes, including reduction in opioid use and HIV risk behaviors (Carrieri et al., 2003; Fudala et al., 2003; Johnson et al., 1995; Johnson, Jaffe, & Fudala, 1992; Johnson et al., 2000; Ling, Wesson, Charuvastra, & Klett, 1996; Lott, Strain, Brooner, Bigelow, & Johnson, 2006; Marsch et al., 2005; Pani, Maremmani, Pirastu, Tagliamonte, & Gessa, 2000; Petitjean et al., 2001; Schottenfeld, Pakes, Oliveto, Ziedonis, & Kosten, 1997; Strain, Stitzer, Liebson, & Bigelow, 1996; Sullivan et al., 2008). Despite these benefits, buprenorphine treatment is not widespread in the United States (Fiellin, 2007). One reason for limited buprenorphine treatment is the challenge patients and providers face with buprenorphine induction (Cunningham, Kunins, Roose, Elam, & Sohler, 2007; Walley et al., 2008).

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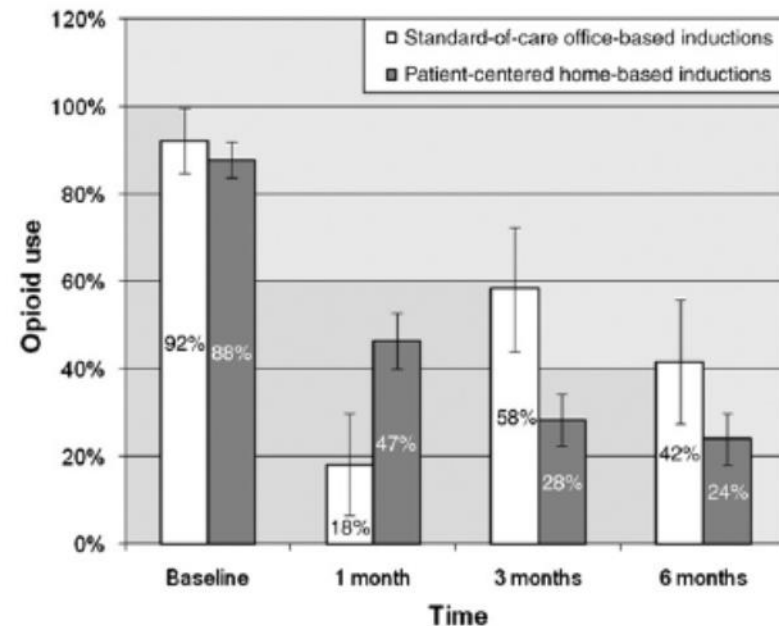


Fig. 1. Opioid use over time by induction strategy.

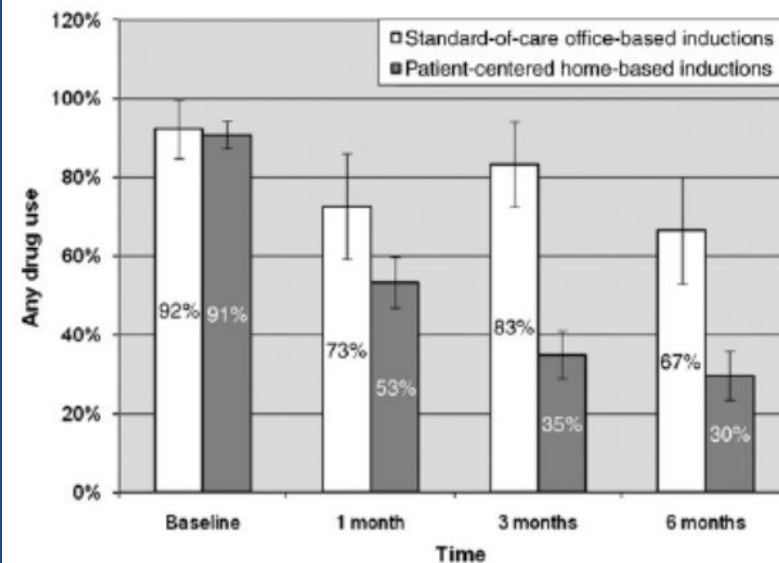


Fig. 2. Any drug use over time by induction strategy.



# Remote Assessment for New Patients

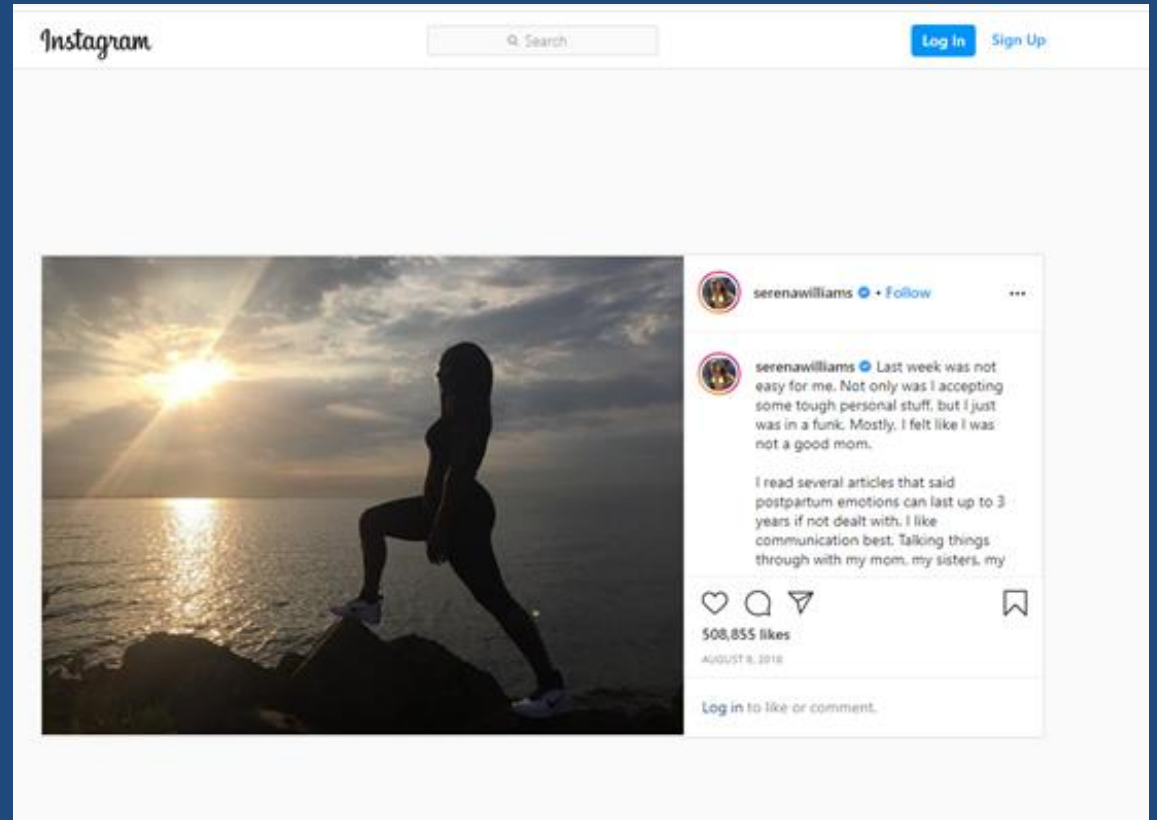
- Establish Diagnosis (DSM-5)
- Review PMP
- History of recent drug use, withdrawal symptoms, etc
- Naloxone co-prescribing
- Consider symptomatic medications for withdrawal
  
- Drug testing (urine, saliva, etc) not essential
- Pregnancy test – not needed for medication initiation for OUD

# Urine Drug Testing: Opportunity for Positive Practice Change

- Increase in tele-services decrease urine drug testing
- Urine drug testing not recommended for assessment of substance use disorder in pregnancy
- Urine testing at time of delivery – problematic
- Addiction Medicine response to COVID-19: Opportunity to rethink role of urine drug testing in prenatal and addiction care

# The 4<sup>th</sup> Trimester - Postpartum

- Critical Period
  - Newborn care, breastfeeding, maternal/infant bonding
  - Mood changes, sleep disturbances, physiologic changes
  - Cultural norms, “the ideal mother” in conflict with what it is actually like to have a newborn
  - Insurance and welfare realignment
- Neglected Period
  - Care shifts from frequent to infrequent
  - From Mom-focused (PNC provider) to Baby-focused (Pediatrician)
  - From “medical” to “social” (WIC)
  - Continuity of Care: Addiction Provider







Contents lists available at ScienceDirect

## Drug and Alcohol Dependence

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## Medication assisted treatment discontinuation in pregnant and postpartum women with opioid use disorder

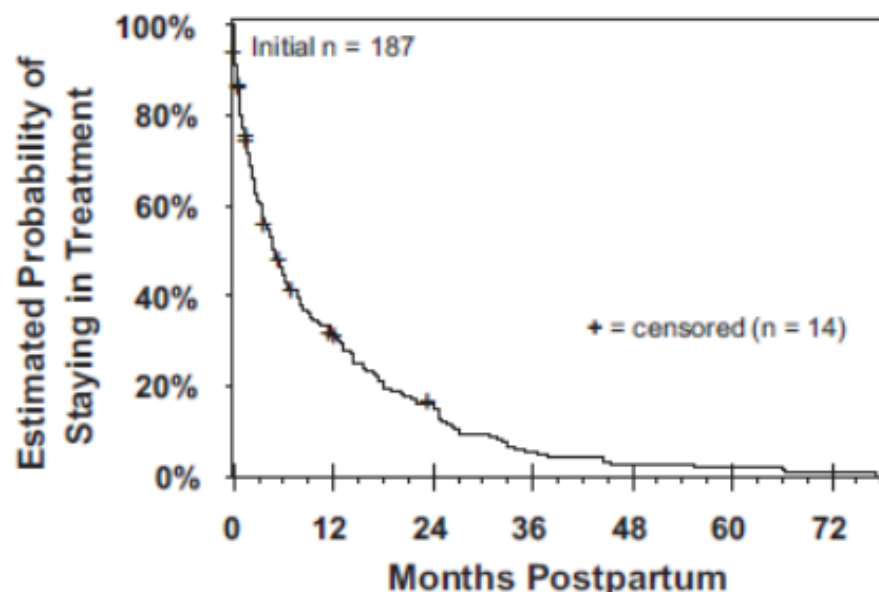
Christine Wilder<sup>a,b,\*</sup>, Daniel Lewis<sup>a</sup>, Theresa Winhusen<sup>a</sup><sup>a</sup> Addiction Sciences Division, Department of Psychiatry and Behavioral Neuroscience, University of Cincinnati College of Medicine, 3131 Harvey Avenue Cincinnati, OH 45229, USA<sup>b</sup> Department of Veterans Affairs Medical Center, 3200 Vine Street, Cincinnati, OH 45220, USA

Fig. 1. Kaplan–Meier estimates for remaining in methadone treatment after pregnancy.

Table 1  
Studies reporting treatment retention results for MAT in pregnant women.

	Location	Sample size	Mean age	Racial composition	Mean EGA (wks) at study entry <sup>a</sup>	MAT medication and dosage information	Discontinuation rates and other treatment attendance results
<b>Randomized controlled trials</b>							
Tuten et al. (2012)	Johns Hopkins Center for Addiction and Pregnancy, Baltimore, MD	n = 133	30.0	71.4% African American, 26.3% Caucasian, 2.3% Biracial	16.1	Methadone, mean dose at delivery = 81.3 mg	Overall: 23% (discontinuation prior to delivery)
Jones et al. (2010)	4 US cities, 2 US rural sites, and Vienna, Austria	n = 175 (methadone = 89, buprenorphine = 86)	28.9	83% Caucasian, 14% African American, 3% Other	18.7	Methadone (51%), mean dose at delivery = 82.9 mg Buprenorphine (49%), mean dose at delivery = 17.2 mg	Overall: 25% (discontinuation prior to delivery) Methadone group: 18% (n = 16) Buprenorphine group: 33% (n = 28)
Jones et al. (2005)	Johns Hopkins Center for Addiction and Pregnancy, Baltimore, MD	n = 30 (methadone = 15, buprenorphine = 15)	30	75% African American, 20% Caucasian, 5% Other	23.2	Methadone (50%), mean dose at delivery = 79.1 mg Buprenorphine (50%), mean dose at delivery = 18.7 mg	Overall: 33% (discontinuation prior to delivery) Methadone group: 27% (n = 4) Buprenorphine group 40% (n = 6)
Jones et al. (2001)		n = 85 (intervention = 47; control = 38)	28	76% African American	23.4	Methadone, mean dose = 42 mg	Overall: 6% (discontinuation within 14 days) Intervention group: 6.4% (n = 3) Control group: 5.3% (n = 2) Among individuals who did not drop out, the intervention group attended a mean of 12.1 days versus the control group which attended a mean of 10.6 days (p < 0.05)
Silverman et al. (2001)		n = 40 (intervention = 20, control = 20)	31.8	83% African American, 17% Caucasian	NR	Methadone, mean dose = 55.5 mg	Overall: 53% (discontinuation within 6 months) Intervention group: 45% Control group: 60% Mean treatment duration was 18.6 wks for intervention group and 15.1 wks for control group (p = 0.17) MAT participants: 13.6% (discontinuation within 30 days)
Svikis et al. (1997) <sup>b</sup>		n = 66 randomized among 4 treatment groups <sup>c</sup>	28.3	80.3% African American	22.5	Methadone, dosing NR	
<b>Cohort studies</b>							
Peles and Adelson (2006)	Tel Aviv, Israel	n = 45 pregnant women (out of total n = 470 for entire cohort)	31.5	78.3% Israeli, 21.7% Immigrant	NR	Methadone, mean dose at end of study period = 141.1	Pregnant women: 22.2% (discontinuation within 1 year; this was not significantly different from the dropout rate of non-pregnant women or of men) Overall 4% (discontinuation prior to delivery) 2% had unavailable outcome information
McCarthy et al. (2005)	Sacramento, CA	n = 94	32	64% Caucasian, 25% Hispanic, 6% African American, 4% Asian, 1% Other	NR	Methadone, mean dose at delivery = 101 mg	24.4% attended 4–7 treatment visits; 23.2% attended 8–14, 25.6% attended 15–26, and 26.8% attended 27–96.
Laken et al. (1997) <sup>b</sup>	Eleonore Hutzel Recovery Program, Detroit, MI	n = 40	29.7	88% African American	26.2	Methadone, dosing NR	44.0% of participants attended no treatment visits; 18.8% attended 1–5 treatment visits; 17.8% attended 6–12 visits, and 20.4% attended 13–62 visits
Laken and Ager (1996) <sup>b</sup>		n = 55	29.6	88% African American	26.1	Methadone, dosing NR	
DePetrillo and Rice (1995)	Location not identified	n = 45	29.3	78% Caucasian, 22% Latin or African American	10.6	Methadone, mean dose at delivery = 52 mg	Overall 0% (discontinuation prior to delivery)
Chappel and Senay (1973)	Special Treatment Unit, Illinois Drug Abuse Program, Chicago, IL	n = 11	NR	NR	NR	Methadone, dosing NR	Overall: 63.6% (discontinuation within 2 years)
<b>Case control studies</b>							
Crandall et al. (2004)	Hennepin Faculty Associates Addiction Medicine Program, Minneapolis, MN	n = 102 (pregnant cases = 51, non-pregnant controls = 51)	29.9	51% Caucasian, 45% African American, 4% Other	NR	Methadone, dosing NR	Pregnant women: 25.5% (discontinuation within 9 months) Average length of participation was 7.7 months out of a maximum of 9 months which was not significantly different from the control group of non-pregnant women
<b>Observational studies</b>							
Fitzsimons et al. (2007)	Johns Hopkins Center for Addiction and Pregnancy, Baltimore, MD	n = 106	30.6	78% African American, 22% Caucasian	14.7	Methadone, mean dose at treatment day 30 = 64 mg	Average number of days that counseling sessions were attended was 57 for individuals with co-occurring anxiety disorder versus 45 for individuals with either a co-occurring mood disorder or no co-occurring disorder, out of a maximum of 84 days (p < 0.01)
Fischer et al. (1998)	University of Vienna Drug Addiction Outpatient Clinic, Vienna, Austria	n = 98	NR	NR	20.1	Methadone (52%), mean dose at delivery = 45 mg Slow release methadone (35%), mean dose at delivery = 259.4 mg Buprenorphine (12%), mean dose at delivery = 6.6 mg	Overall: 0% (discontinuation prior to termination of pregnancy or delivery)

# Fatal and Nonfatal Overdose Among Pregnant and Postpartum Women in Massachusetts

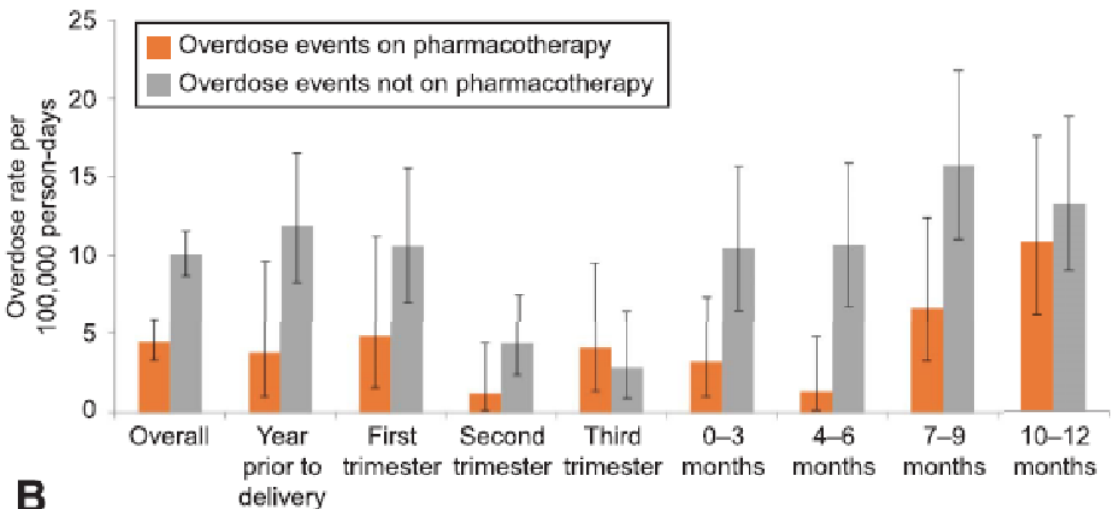
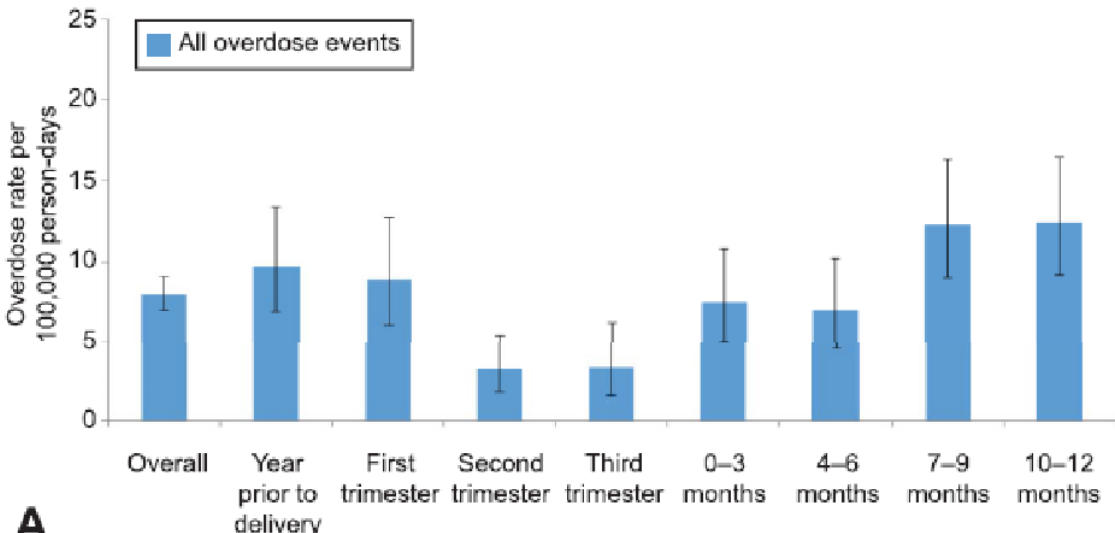
OBSTETRICS & GYNECOLOGY

*David M. Schiff, MD, MSc, Timothy Nielsen, MPH, Mishka Terplan, MD, MPH, Malena Hood, MPH, Dana Bernson, MPH, Hafsatou Diop, MD, MPH, Monica Bharel, MD, MPH, Timothy E. Wilens, MD, Marc LaRochelle, MD, MPH, Alexander Y. Walley, MD, MSc, and Thomas Land, PhD*

Table 2. Opioid Overdose Rates Among Pregnant and Parenting Women With Evidence of Opioid Use Disorder in the Year Before Delivery (n=4,154)

Period Relative to Delivery	All OD Events	OD Events While Receiving Pharmacotherapy	OD Events Not Receiving Pharmacotherapy
Overall	7.99 (7.01–9.06)	4.43 (3.28–5.86)*	10.04 (8.67–11.56)*
Year before delivery–conception	9.72 (6.91–13.29)	3.74 (1.02–9.57)	11.89 (8.28–16.54)
Trimester (weeks of gestation)			
1st (0–12)	8.88 (6.04–12.61)	4.79 (1.56–11.18)	10.63 (6.94–15.58)
2nd (13–28)	3.23 (1.81–5.32)	1.20 (0.15–4.35)	4.35 (2.32–7.44)
3rd (29 or greater)	3.32 (1.59–6.10) <sup>†</sup>	4.08 (1.32–9.51)	2.80 (0.91–6.53)
Postpartum (mo)			
0–3	7.41 (4.92–10.71)	3.17 (1.03–7.41)	10.44 (6.62–15.67)
4–6	6.89 (4.50–10.10)	1.31 (0.16–4.74)*	10.67 (6.84–15.88)*
7–9	12.2 (8.93–16.28) <sup>†</sup>	6.74 (3.23–12.40)	15.75 (11.03–21.80)
10–12	12.35 (9.07–16.42) <sup>†</sup>	10.84 (6.20–17.60)	13.3 (9.04–18.88)

OD, opioid overdose.  
Data are rate/100,000 person-days (95% CI).  
\* Denotes statistically significant difference between overdose rates among women receiving pharmacotherapy vs women not receiving pharmacotherapy.  
<sup>†</sup> Denotes statistically significant difference between overall overdose rates during third trimester and 7–12 months postpartum.



# Postpartum Issues

- Breast Feeding:  
Attachment and Neonatal Abstinence Syndrome management (ESC)  
vs  
COVID-19 hospital policies
- Contraception:  
Sterilization at time of delivery  
Postpartum LARC
- Medication and addiction treatment continuation  
Telehealth for Postpartum Visits





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When Separation is not the Answer: Breastfeeding Mothers and Infants affected by COVID-19

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#### Key words

COVID-19; SARS-CoV-2; Separation; Breastfeeding

#### Author contributions

The authors initiated the manuscript via group discussion. Tomori and Gribble drafted the initial versions and Palmquist, Ververs and Gross provided additional input and revisions. All authors agreed to the final manuscript.

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#### Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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## Abstract

The World Health Organisation (WHO) has provided detailed guidance on the care of infants of women who are a person under investigation (PUI) or confirmed to have COVID-19, which supports immediate postpartum mother-infant contact and breastfeeding with appropriate respiratory precautions. Although many countries have followed WHO guidance, others have implemented infection prevention and control policies (IPC) that impose varying levels of postpartum separation and discourage or prohibit breastfeeding or provision of expressed breastmilk. These policies aim to protect infants from the potential harm of infection from their mothers, yet they may fail to fully account for the impact of separation. Global COVID-19 data are suggestive of potentially lower susceptibility and a typically milder course of disease among children, although the potential for severe disease in infancy remains. Separation causes cumulative harms, including disrupting breastfeeding and limiting its protection against infectious disease, which has disproportionate impacts on vulnerable infants. Separation also presumes the replaceability of breastfeeding – a risk that is magnified in emergencies. Moreover, separation does not ensure lower viral exposure during hospitalizations and post-discharge, and contributes to the burden on overwhelmed health systems. Finally, separation magnifies maternal health consequences of insufficient breastfeeding and compounds trauma in communities who have experienced long-standing inequities and violence, including family separation. Taken together, separating PUI/confirmed SARS-CoV-2 positive mothers and their infants may lead to excess preventable illnesses and deaths among infants and women around the world. Health services must consider the short-and-long-term impacts of separating mothers and infants in their policies.

## Key Words

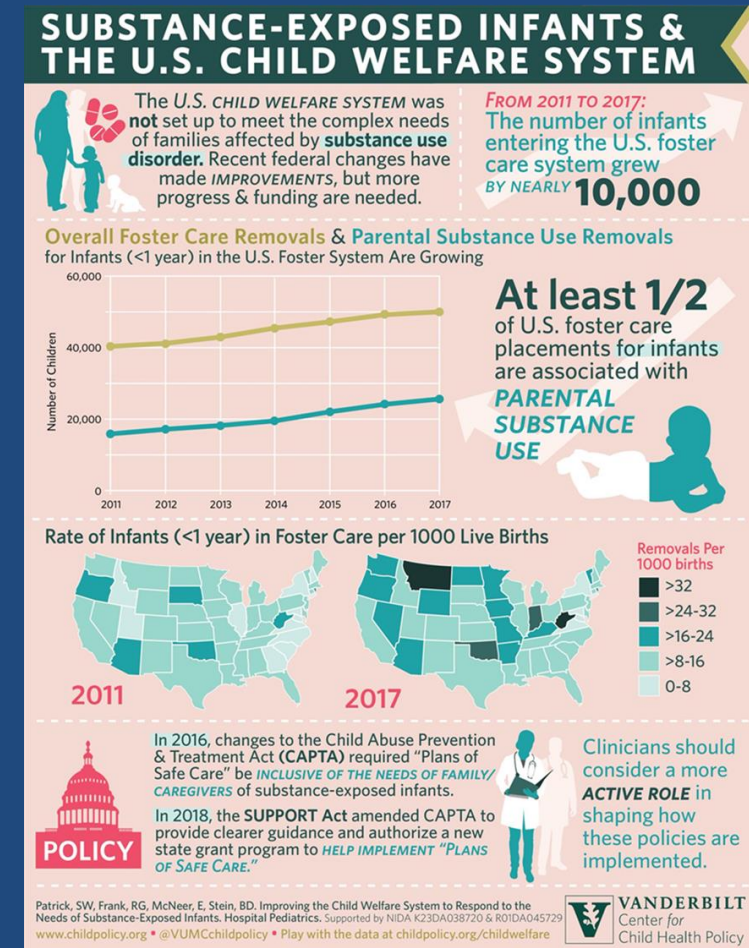
COVID-19; SARS-CoV-2; Mother-infant separation; Breastfeeding

## Key Messages

1. The World Health Organization has provided comprehensive guidance that promotes proximity and breastfeeding for mothers and infants affected by COVID-19.
2. Some settings followed WHO guidance, while others implemented policies that impose separation on COVID-19-affected mothers and infants.
3. Separation policies aim to protect infants from potential harm from maternal infection with SARS-CoV-2, but fail to account for the impacts of separation.
4. Separation policies have detrimental effects on breastfeeding, and do not ensure lower viral exposure, resulting in potential excess deaths.
5. Health services must consider the full impacts of separating mothers and infants in their policies.

# Child Welfare: Concerning Trends

- Opioid Crisis and Foster Care Epidemic
- Racial Inequities Along Child Welfare Continuum
- COVID-19 Response:
  - Delay in Family Court Hearings
  - Denial of Visitation for Parents
  - Insistence on Tele-visits for Newborns (!)
  - In context of continued increase in reporting and removals

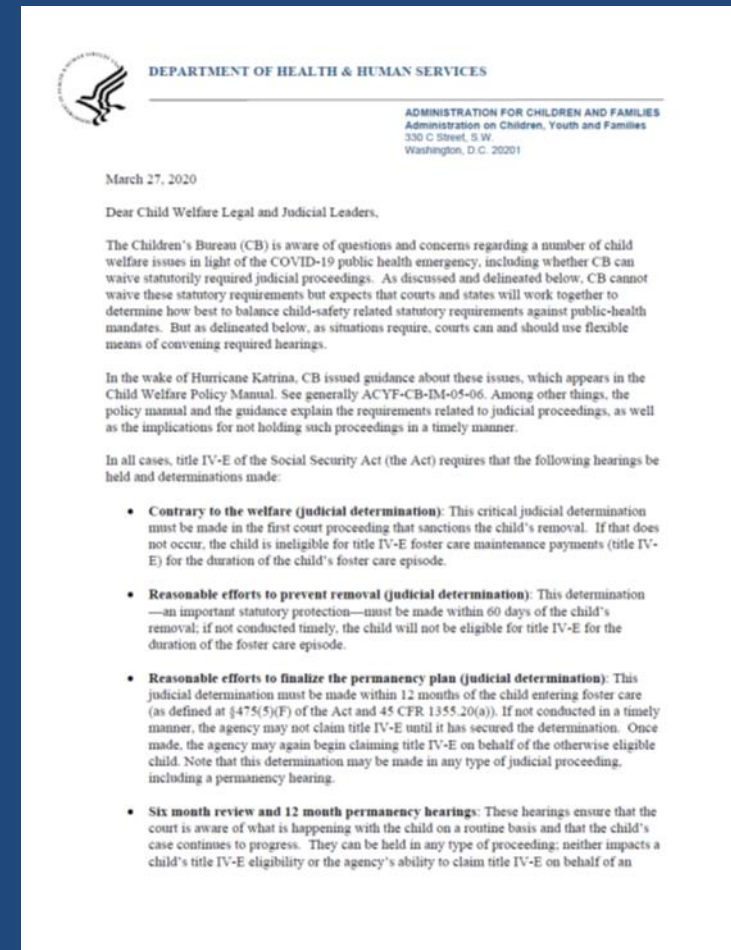




# Child Welfare: Concerning Trends

- Children's Bureau Response:

- Refrain from making sweeping, blanket orders ceasing, suspending, or postponing court hearings;
- Ensure that important decisions about when and how hearings are conducted are made on a case-by-case basis in accordance with the facts of each individual matter;
- Encourage attorneys to file written motions raising issues of immediate concern;
- Make maximum use of technology to ensure due process where in-person hearings are not possible or appropriate;
- Ensure parents and youth have access to technology such as cell phones, tablets, or computers with internet access to participate in hearings or reviews and maintain important familial connections;
- Consider utilizing CIP funds to support and enhance virtual participation for parents, children, youth, and their attorneys in hearings and reviews; and
- Encourage attorneys to resolve agreed-upon issues via stipulated orders. For example, if all parties agreed that a child in foster care can be reunified with his/her family immediately, that issue should be resolved via a stipulated order, rather than waiting weeks or months for an in-person court hearing.





## Overdose: Concerning Trends

Week	Count of ED Visits			Rate per 10k ED Visits		
	Opioid or Unspecified	Heroin	All Drug	Opioid or Unspecified	Heroin	All Drug
March 1 -7	187	37	351	26.7	5.3	50.1
March 8-14	172	33	328	24.5	4.7	46.8
March 15-21	183	28	323	33.0	5.1	58.3
March 22-28	142	32	260	32.1	7.2	58.8
March 29-April 4	155	31	270	41.2	8.2	71.7
April 5-11	152	29	283	41.9	8.0	78.0
April 12-18	153	33	294	42.1	9.1	80.9
April 19-25	167	28	314	43.4	7.3	81.6

Count of ED Visits and the Rate per 10k of ED visits for Unintentional Overdose by Opioid or Unspecified, Heroin and All Drug for Virginia state by Week,

# Don't Forget Naloxone!

- Remember to co-prescribe naloxone
- Naloxone availability may be decreased due to fewer public health and community-based organization efforts
- Overdose may increase due to social isolation
- Therefore make sure everyone has naloxone
- Consider asking all patients if they need naloxone script

# Conclusions

- Opportunities and Unintended Consequences for pregnant people with OUD during COVID19
- Sheltering in place and isolation – potential triggers for people with OUD
- As providers, need to start discussing what care looks like post COVID19 :  
The telefuture of telehealth



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Free and confidential clinician-to-clinician telephone advice focusing on substance use evaluation and management for primary care clinicians.

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Learn more at <http://nccc.ucsf.edu/clinical-resources/substance-use-management/>



*This project is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U10HA30039-01-00 (AIDS Education and Training Centers National Clinician Consultation Center) in partnership with the HRSA Bureau of Primary Health Care (BPHC) awarded to the University of California, San Francisco.*

Treating Homeless Opioid Dependent Patients with Buprenorphine in an Office-Based Setting

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**CONTEXT:** Although office-based opioid treatment with buprenorphine (OBOT-B) has been successfully implemented in primary care settings in the US, its use has not been reported in homeless patients.

**OBJECTIVE:** To characterize the feasibility of OBOT-B in homeless relative to housed patients.

**DESIGN:** A retrospective record review examining treatment failure, drug use, utilization of substance abuse treatment services, and intensity of clinical support by a nurse care manager (NCM) among homeless and housed patients in an OBOT-B program between August 2003 and October 2004. Treatment failure was defined as elopement before completing medication induction, discharge after medication induction due to ongoing drug use with concurrent nonadherence with intensified treatment, or discharge due to disruptive behavior.

**RESULTS:** Of 44 homeless and 41 housed patients enrolled over 12 months, homeless patients were more likely to be older, nonwhite, unemployed, infected with HIV and hepatitis C, and report a psychiatric illness. Homeless patients had fewer social supports and more chronic substance abuse histories with a 3- to 6-fold greater number of years of drug use, number of detoxification attempts and percentage with a history of methadone maintenance treatment. The proportion of subjects with treatment failure for the homeless (21%) and housed (22%) did not differ ( $P=.94$ ). At 12 months, both groups had similar proportions with illicit opioid use [Odds ratio (OR), 0.9 (95% CI, 0.5–1.7)  $P=.8$ ], utilization of counseling (homeless, 46%; housed, 49%;  $P=.95$ ), and participation in mutual-help groups (homeless, 25%; housed, 29%;  $P=.96$ ). At 12 months, 36% of the homeless group was no longer homeless. During the first month of treatment, homeless patients required more clinical support from the NCM than housed patients.

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**CONCLUSIONS:** Despite homeless patients' social instability, greater chronic drug use, office-based treatment with buprenorphine was effective in a population comparable to outpatient treatment with respect to treatment failure and utilization of substance abuse treatment services.

**KEY WORDS:** buprenorphine; drug dependence; homelessness.  
DOI: 10.1007/s11606-006-0023-1  
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INTRODUCTION

Opioid abuse persists as a pervasive problem in the United States, both heroin and prescription analgesics.<sup>1,2</sup> Opioid agonist treatment with buprenorphine is effective for treatment of opioid dependence, and primary care physicians in the United States gained the opportunity to treat dependent patients in primary care settings referred to as office-based opioid treatment (OBOT).

In 2003, the primary care clinic (BMC) implemented an OBOT program employing collaborative care with a nurse care manager (NCM).<sup>15</sup> The primary care clinic OBOT-B program provided housing, as clinical guidelines recommend, as an entry criterion for treatment and stability as a criterion for OBOT-B. The program treated a population with a high prevalence of chronic illness and death.<sup>22</sup>

Unique challenges confront homeless persons in substance abuse treatment,<sup>26</sup> their high rates of treatment failure, and the fact that homeless persons are correlated with support; unstable living environments; drug dependence.<sup>29,30</sup> However, homeless persons' success in substance abuse treatment can increase under supportive circumstances.<sup>30,31</sup> Furthermore, despite limited literature on methadone treatment in homeless populations, published data suggest greater success with

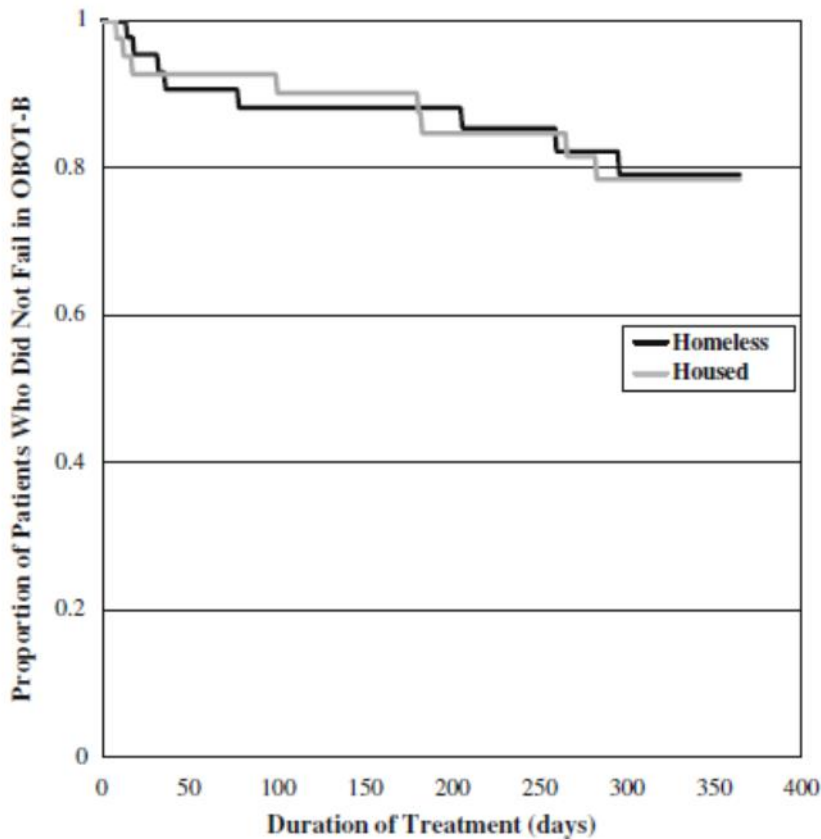


Figure 1. Kaplan-Meier estimates of the proportion of homeless and housed patients who did not fail office-based opioid treatment with buprenorphine.  $P=.94$  for the comparison between homeless and housed subjects by the log-rank test.

Table 3. Outcomes of Homeless ( $N=44$ ) and Housed ( $N=41$ ) Patients after 12-months of Office-Based Opioid Treatment with Buprenorphine

	Homeless N (%)	Housed N (%)	P-value
Attending counseling <sup>†</sup>			0.95
Yes	20 (46)	20 (49)	
No	4 (9)	4 (10)	
Unknown	20 (46)	17 (42)	
Attending mutual help groups <sup>†</sup>			0.96
Yes	11 (25)	12 (29)	
No	13 (30)	12 (29)	
Unknown	20 (46)	17 (42)	
Currently homeless <sup>††</sup>			0.03
Yes	8 (18)	1 (2)	
No	16 (36)	23 (56)	
Unknown	20 (46)	17 (42)	
Currently employed <sup>§</sup>			0.07
Yes	17 (39)	23 (56)	
No	7 (16)	1 (2)	
Unknown	20 (46)	17 (42)	
Involvement of social support in care <sup>  </sup>			0.50
Yes	22 (50)	24 (59)	
No	2 (5)	0 (0)	
Unknown	20 (46)	17 (42)	





## Short Communication

## Unobserved versus observed office buprenorphine/naloxone induction: A pilot randomized clinical trial

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## ABSTRACT

Physician adoption of buprenorphine treatment of opioid dependence may be limited in part by concerns regarding the induction process. Although national guidelines recommend observed induction, some physicians utilize unobserved induction outside the office. The aim of this pilot randomized clinical trial was to assess preliminary safety and effectiveness of unobserved versus observed office buprenorphine/naloxone induction among patients entering a 12-week primary care maintenance study. Participants ( $N=20$ ) with DSM-IV opioid dependence were randomly assigned to unobserved or office induction, stratifying by past buprenorphine use. All patients received verbal and written instructions. A withdrawal scale was used during initiation and to monitor treatment response. Clinic visits occurred weekly for 4 weeks then decreased to monthly. The primary outcome, successful induction one week after the initial clinic visit, was defined as retention in buprenorphine/naloxone treatment and being withdrawal free. Secondary outcomes included prolonged withdrawal beyond 2 days after medication initiation and stabilization at week 4, defined as being in treatment without illicit opioid use for the preceding 2 weeks. Outcome results were similar in the two groups: 6/10 (60%) successfully inducted in each group, 3/10 (30%) experienced prolonged withdrawal, and 4/10 (40%) stabilized by week 4. These pilot study results suggest comparable safety and effectiveness of unobserved and office induction and point toward utilization of non-inferiority design during future definitive protocol development. By addressing an important barrier for physician adoption, further validation of the unobserved buprenorphine induction method will hopefully lead to increased availability of effective opioid dependence treatment.

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Opioid dependence remains an undertreated public health problem. Approximately 800,000 individuals are heroin dependent in the U.S. (Lloyd, 2003), while 1.7 million reported a prescription opioid use disorder in 2007 (SAMHSA, 2008). Unfortunately, methadone maintenance is only available to approximately 250,000 patients at unevenly geographically dispersed programs (DASIS, 2006). Office-based treatment with buprenorphine (BUP) and buprenorphine–naloxone (BUP/NX) has been available in the U.S. since 2002. Increasing evidence supports buprenorphine treatment as an effective means of expanding access in general office settings (Gunderson and Fiellin, 2008). However, physician adoption has primarily been among addiction specialists who make up the majority of prescribers (Fiellin, 2007), and opioid dependence remains largely untreated.

Strategies to improve dissemination in general practice are urgently needed given the substantial morbidity of untreated opioid dependence (Hser, Hoffman, Grella, & Anglin, 2001). One important barrier for uptake involves physician concern about buprenorphine induction particularly among novice prescribers (Barry et al., 2009; Gunderson, Fiellin, Levin, Sullivan, & Kleber, 2006; Kissin, McLeod, Sonneck, & Stanton, 2006; Netherland et al., 2009; Walley et al., 2008). The induction barrier is due in part to potential for precipitated opioid withdrawal if the first buprenorphine doses occur before the patient is in spontaneous opioid withdrawal. In addition, national practice guidelines recommend office initiation with observation and monitoring for up to 2 h, which could significantly impact physician and ancillary staff workload (CSAT, 2004). Perhaps as a consequence, some prescribers initiate buprenorphine outside the office (Walley et al., 2008). Although descriptive data suggest the feasibility of unobserved “home” induction with clinician phone support in primary care (Alford et al., 2007; Lee, Grossman, DiRocco, & Gourevitch, 2009; Mintzer et al., 2007; Soeffing, Marting, Fingerhood, Jasinski, & Rastegar, 2009; Sohler et al., 2009), comparative effectiveness data are

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Table 2

Buprenorphine dosing and phone contacts.

	Office	Unobserved	p value
Buprenorphine dose, mg <sup>a</sup>			
Induction Day 1	10 (5)	14 (5)	$p = 0.08$
Week 2	13 (5)	14 (6)	NS
Week 3	9 (10)	16 (5)	NS
Week 4	11 (6)	14 (5)	NS
Week 8	10 (7)	13 (7)	NS
Week 12	10 (6)	7 (1)	NS
Phone call number <sup>a</sup>			
Week 1	4.1 (1.9)	6.4 (5.6)	NS
Week 2	0.7 (1.3)	0.8 (1.0)	NS
Week 3	0.2 (0.4)	0.1 (0.3)	NS
Week 4	0.1 (0.3)	0.0 (0.0)	NS
Phone call minutes <sup>a</sup>			
Week 1	3.4 (0.9)	4.3 (1.6)	NS
Week 2	2.5 (1.5)	2.5 (1.3)	NS
Week 3	2.5 (0.7)	3.0 (NA)	NS
Week 4	1.0		

NS = non-significant.

<sup>a</sup> Data presented are means  $\pm$  standard deviation.

60% completed Week 1 in each group